Newborn Screening Quality Assurance Program

2008 ANNUAL SUMMARY REPORT

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Celebrating 30 Years of Service

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention (CDC)
and the
Association of Public Health Laboratories

FROM THE

EDITOR

W. Harry Hannon, PhD . . . An Iconic Trailblazer in Newborn Screening

Dr. Harry Hannon has been the only director of CDC's Newborn Screening Quality Assurance Program (NSQAP) for more than 30 years. I have known him most of that time. Long ago, I recognized that he was one-of-a-kind when I asked, "What does the *W* in your name stand for?" He grinned and replied, "Wild." He has been interviewed and written about many times, and there is much documentation of his far-reaching scientific accomplishments. Most people who work in the newborn screening world have heard of him and his many achievements. I'd like to offer a different peek at this iconic trailblazer: a glance at the whole person who is W. Harry Hannon.

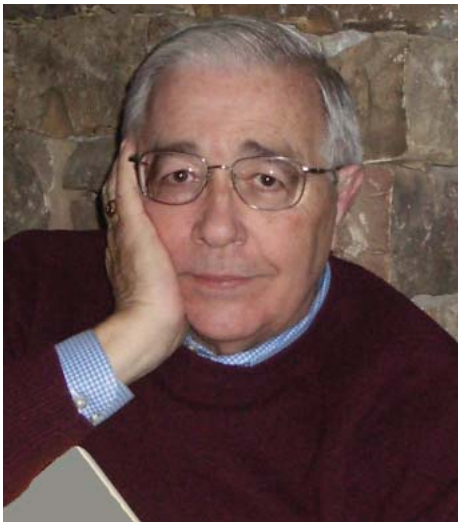

Photo by Carol Bell

Harry is intellectual, meticulous, mischievous, and altruistic. These core qualities resonate in all that he does. He enjoys conversation and a good debate on disparate topics that range from science to sports to spots. He is a quick wit who enjoys throwing an occasional light-hearted jab. He can't stand clutter, and after all these years, he still frets over oral presentations. He is forever making changes to the last change, always seeking a better and still better way to express his thoughts.

He drives a big blue pickup truck, and he is a University of Tennessee football fan who can't bear to watch the game when it becomes heart-stopping. In the many ethnic restaurants near CDC, he makes daring lunchtime food choices just because he's curious.

He is a good poet and a family historian. His dedication to CDC and newborn screening has kept him from fully pursuing these interests, so retirement may finally award him the time to chase his hobbies.

He speaks of his mother often and always with love. I think his drive came from her. His most heartwarming quality is that he is the best grandpa in the world. He adores his five grandchildren and spends much time with them. With the benefit of his influence, maybe one of them will grow up to be a world-class scientist too.

It's hard to imagine how NSQAP will be without Harry, but he is leaving a solid foundation to build on and high standards to attain.

Harry, we wish you a Happy Retirement.

Carol J. Bell

Editor and Program Administrator

NSQAP Contents

THE COVER

Font size in the word cloud is proportional to number of participants in each country. www.wordle.net

Program Information Web site:
http://www.cdc.gov/labstandards/nsqap.htm

Data-reporting Web site:
http://wwwn.cdc.gov/nsqap/public/default.aspx

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INTRODUCTION

The Newborn Screening Quality Assurance Program (NSQAP) is designed to help screening laboratories achieve excellent technical proficiency and maintain confidence in their performance while processing large volumes of specimens daily. We continually strive to produce certified dried-blood spot (DBS) materials for reference and quality control (QC) analysis, to improve the quality and scope of our services, and to provide immediate consultative assistance. Through our interactive efforts with the program's participants, we aspire to meet their growing and changing needs. We always welcome comments and suggestions on how we may better serve the newborn screening laboratories.

A major public health responsibility, newborn screening for detection of treatable, inherited metabolic diseases is a system consisting of six parts: education, screening, follow-up, diagnosis, management, and evaluation. Effective screening of newborns using DBS specimens collected at birth, combined with follow-up diagnostic studies and treatment, helps prevent mental retardation and premature death. These blood specimens are collected routinely from more than 98% of all newborns in the United States. State public health laboratories or their associated laboratories routinely screen DBS specimens for inborn errors of metabolism and other disorders that require intervention. For more than 30 years, the Centers for Disease Control and Prevention (CDC), with its cosponsor, the Association of Public Health Laboratories (APHL), has conducted research on materials development and assisted laboratories with quality assurance (QA) for these DBS screening tests. The QA services primarily support newborn screening tests performed by state laboratories; however, we also accept other laboratories and international participants into the QA program. All laboratories in the United States that test DBS specimens participate voluntarily in NSQAP. The program provides QA services for congenital hypothyroidism, phenylketonuria, galactosemia, congenital adrenal hyperplasia, maple syrup urine disease, homocystinuria, tyrosinemia, citrullinemia, biotinidase deficiency, cystic fibrosis (CF), and hemoglobinopathies. QA services are also provided for urea cycle disorders, fatty acid oxidation disorders, and organic acid metabolic disorders.

The QA program consists of two DBS distribution components: QC materials for periodic use and quarterly proficiency testing (PT). The QC program enables laboratories to achieve high levels of technical proficiency and continuity that transcend changes in commercial assay reagents while maintaining the requisite high-

volume specimen throughput. The QC materials, which are intended to supplement the participants' method- or kit-control materials, allow participants to monitor the long-term stability of their assays. The PT program provides laboratories with quarterly panels of blind-coded DBS specimens and gives each laboratory an independent external assessment of its performance. DBS materials for QC and PT are certified for homogeneity, accuracy, stability, and suitability for all kits manufactured by different commercial sources.

Over the last ten years, NSQAP has grown substantially, both in the number of participants and in the scope of global participation. In 2008, 418 newborn screening laboratories in 62 countries (at least one laboratory per country) were active program participants (see front cover: font size is proportional to number of participants); of these, 344 participated in the PT component (Figure 1) and 334 in the QC part (Figure 2). One hundred eighty-seven laboratories reported PT data using tandem mass spectrometry (MS/MS). Of these, 51 were domestic laboratories. MS/MS has made a major impact on the data reported to NSQAP. DBS materials for 31 analytes, covering primary markers for 44 disorders, were distributed to participating laboratories (Figures 1–2). This report presents an overview of all phases of the PT program and summarizes all QC data reported in 2008. For biotinidase, galactose-1-phosphate uridyltransferase (GALT) deficiency, and hemoglobins, QC materials were not distributed because of the limited availability of appropriate blood sources.

NEW ACTIVITIES

In April, UDOT, a new PT panel, replaced one of the PT events within NSQAP's routine quarterly PT program. Seventy-one laboratories in the United States and Canada participated. All interactions between NSQAP and participants were handled completely by e-mail. There was a two-week time period between shipping day and data deadline. Post-event comments from most participants were very favorable mostly because the PT simulated screening practice. The report for this program can be found online at http://www.cdc.gov/labstandards/nsqap_reports.htm.

NSQAP continued a pilot PT program for laboratories testing DBS for IgM antibodies to *Toxoplasma gondii*. The program had eleven participants; most were from outside the United States. Quarterly reports for this program can be found online at http://www.cdc.gov/labstandards/nsqap_reports.htm.

A few years ago APHL organized a subcommittee of the Newborn Screening and Genetics in Public Health Committee for quality assurance/quality control/proficiency testing. One mission component of the subcommittee is to provide guidance to the NSQAP on procedures, policies, and activities for the quality assessment of laboratory testing. In February and in September 2008, this subcommittee held meetings in Atlanta, where the members discussed current issues. We believe that input from this subcommittee will enhance our continuing efforts to better serve our participants.

In July, NSQAP celebrated 30 years of service to newborn screening laboratories worldwide. Those many years ago, we started QA testing for 31 laboratories in the United States and one disorder. Today we provide QA products for over 400 laboratories in 62 countries testing 44 disorders. We are proud of our long history of public service.

In July, the NSQAP PT data-reporting Web site was upgraded to include data-reporting for C3DC, C10:1, and C14:1. In October, data-reporting for IRT and SUAC was added online along with increased security, which was required by CDC. We have obtained full CDC Certification and Accreditation for the Web site.

NSQAP previously offered an IRT/DNA PT panel along with a separate CF Mutations PT panel. The demand was growing for testing more mutations in addition to Δ F508 (p.Phe508del), and data-reporting for IRT was scheduled to go online; so in July we dropped DNA in combination with IRT and offered only the separate CF Mutations Detection PT to cover this test. Table 5 summarizes the 2008 operation. The number of participants grew to 37 by the end of the year. The quarterly DNA data are summarized in reports posted at http://www.cdc.gov/labstandards/nsqap_reports.htm.

NSQAP received 3112 QC data forms during the data-reporting period that ended November 1, 2008. In 2007, we began development of a paperless QC data-reporting system through Excel file or PDF file by e-mail. We worked on the system throughout 2008, completed it in December, and launched it in January 2009. We urge everyone to report QC data by the new e-mail data-reporting system. For more information, contact Nancy Meredith at nkm1@cdc.gov.

In 2008, NSQAP cosponsored (1) with APHL and the National Newborn Screening and Genetics Resource Center (NNSGRC), a DNA training program, *Newborn Screening Molecular Training Workshop: Using Cystic Fibrosis as a Model*, held in Austin, TX, Madison, WI, and Jamaica Plain, MA; (2) with APHL and NNSGRC, MS/MS training programs: *Translating MS/MS Results*

2008
NSQAP
BY THE NUMBERS

100 percentage of states covered

62 countries participated

851,380 DBS produced

28 employees

44 new enrollments

20 labs moved to inactive status

427 labs enrolled at year end

418 labs reported data

344 labs participated in PT

334 labs participated in QC

21 reports provided to participants

3 filter paper lots evaluated

31 US labs participated when NSQAP was established in 1978

Source: Newborn Screening Quality Assurance Program, December 2008

from Laboratory to Follow-up at the Biochemical Genetics Laboratory, Duke University Medical Center, Research Triangle Park, NC, and *Newborn Screening by MS/MS: Understanding Laboratory Issues and Interpreting Test Results* at the Institute of Metabolic Disease, Baylor University Medical Center, Dallas, TX; (3) with APHL, the National Newborn Screening and Genetic Testing Symposium in San Antonio, TX; and (4) with APHL and CDC's National Center on Birth Defects and Developmental Disabilities, the National Contingency Planning for Newborn Screening Stakeholders Workgroup Meeting in Atlanta, GA. For information about these programs, contact Jelili Ojodu at jelili.ojodu@aphl.org.

NSQAP continued the pilot PT program to investigate materials and clinical interpretations, based on the ratio of 17-OHP, androstenedione, cortisol, and 11-deoxycortisol for second tier CAH screening using LC-MS/MS. A new analyte, 21-deoxycortisol, was added to the PT panel. Six laboratories in the United States participated in the surveys. A poster, *Proficiency Testing for Second Tier CAH Screening – Towards Harmonization of Results*, will be presented at the 6th ISNS European Regional Meeting, to be held in Prague, Czech Republic, in April 2009.

In 2008, Harry Hannon, NSQAP chief, received CLSI's Russell J. Eilers Memorial Award and APHL's Lifetime Achievement Award. To top it off, APHL created the Harry Hannon Laboratory Improvement Award in Newborn Screening ("the Harry"). It was awarded for the first time recently at the Newborn Screening and Genetic Testing Symposium to Gary Hoffman, Wisconsin State Laboratory of Hygiene, Madison, WI, for significant contributions having a direct effect in improving the quality of laboratory results for the newborn screening system. The award was sponsored by Astoria-Pacific. After all these accolades, Dr. Hannon retired on January 2, 2009.

NEWBORN SCREENING TRANSLATION RESEARCH INITIATIVE

The CDC Newborn Screening Translation Research Initiative (NSTRI) completed its third year of operation in 2008. NSTRI is an ongoing collaboration between the CDC Foundation and the CDC Newborn Screening and Molecular Biology Branch. The vision of NSTRI is the methodical expansion of newborn screening to detect more conditions in more infants around the world so all babies with congenital disorders have a better chance for a healthy childhood. The mission of NSTRI is to assemble public, academic, foundation, and corporate partnerships for the scientific and financial support of translational research efforts in newborn screening.

FIGURE 1. Number of Participants in Proficiency Testing Program, 2008
Total = 344

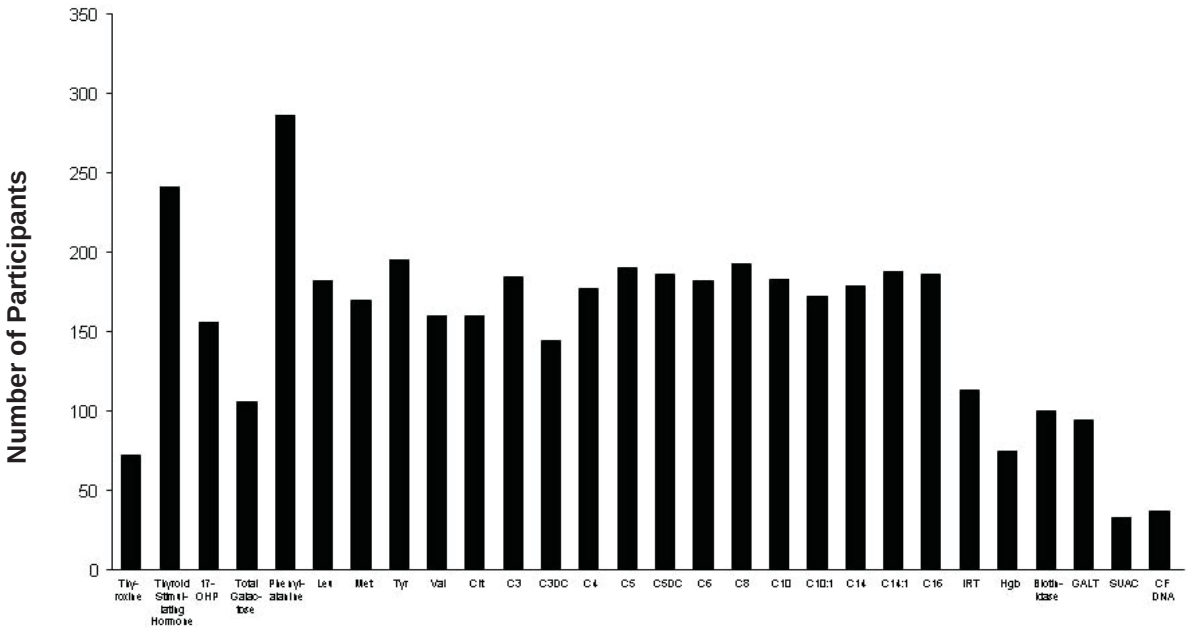
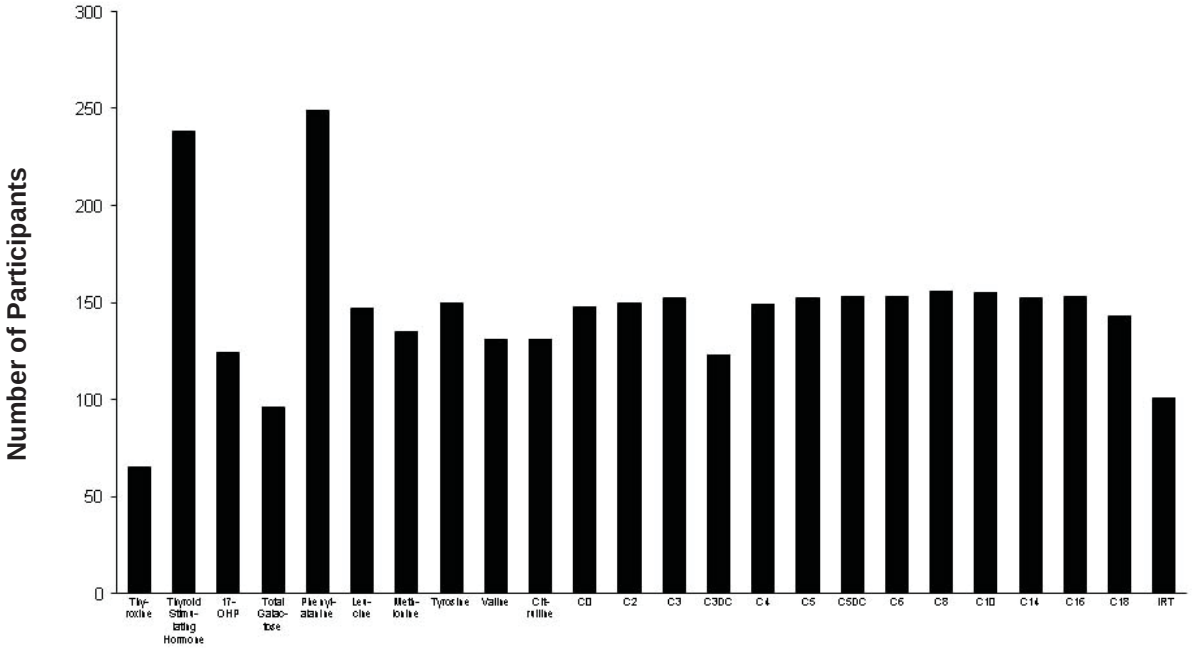


FIGURE 2. Number of Participants in Quality Control Program, 2008
Total = 334



Translation research is often described as the process of moving biomedical research findings "from bench to bedside," but a better description for NSTRI would be "from bench to bassinet." One of the most critical processes in translating laboratory research methods to practical newborn screening assays is the integration of quality assurance systems. The ultimate goal of NSTRI is to help transform research methods into routine assays that become part of NSQAP as they are adapted for routine population-based newborn screening.

During its third year of operation, NSTRI pursued projects focused on several disorders and the innovative laboratory methods to detect newborn biomarkers for them. In addition to corporate, academic, and foundation partners, all projects included collaboration with public health newborn screening programs. The disorders that were targeted in these projects included lysosomal storage disorders (LSD), severe combined immune deficiency (SCID), and neuromental disorders such as epilepsy and autism. More than a dozen partnerships were involved in these projects, and many of the partners contributed both scientific and financial support. Perhaps the most exciting development in 2008 was the Congressionally allocated funding for pilot programs to screen for SCID, made possible through efforts by the Jeffrey Modell Foundation. Awards to two newborn screening programs were issued in September, one to Wisconsin and the other to Massachusetts.

NSTRI and its partners conducted a round robin investigation to evaluate the DBS QC materials developed by CDC and NSTRI staff. Results showed agreement between the four participating laboratories, evidencing the suitability of the materials for use as control materials for LSDs, as well as the robustness of the MS/MS assay. A manuscript detailing the findings has been published recently by Clinical Chemistry (Clin Chem 2009:55; 158–164).

A new staff member has joined NSTRI to perform the day-to-day operations of the LSD program. Dr. Hui Zhou comes from the Emory Department of Human Genetics bringing her experience in LSD patient diagnosis. Moreover, she currently serves on a Workgroup that guides the Georgia Public Health Laboratory with its cut-off determinations.

In addition to the MS/MS assays, NSTRI staff is working to set up fluorometric LSD assays for which there is no MS/MS assay, such as metachromatic leukodystrophy (MLD). This will be done to help characterize patient samples that we may receive from partners such as the University of North Carolina at Chapel Hill and Stanford University, as well as to expand the characterization of our QA materials for diseases beyond the MS/MS assay.

7 New countries joined NSQAP: Egypt, Guatemala, Pakistan, Panama, United Arab Emirates, Uruguay, and Venezuela

For more information about NSTRI or any of its current projects, please contact Robert Vogt at rvogt@cdc.gov. Ideas for new projects and partnerships are welcomed.

FILTER PAPER

The paper disk that is punched to aliquot DBS specimens is a volumetric measurement that requires a degree of uniformity among and within production lots. As part of the QA program, we used an isotopic method[1] developed at CDC to evaluate and compare different lots of filter paper. Mean counts per minute of added isotope-labeled thyroxine (T_4) within a 1/8-inch disk were equated with the serum volume of the disks from the dried whole blood specimens. In comparing production lots, we used statistical analyses of the counting data to determine values for homogeneity, absorption time, and serum absorption of the disks. Lysed-cell whole blood was used initially to avoid variability contributed by uncontrolled red blood cell (RBC) lysis during the 4-day QC production span. Results of later studies concluded that RBC lysis occurring during processing of the intact-cell blood pools was not sufficient to contribute substantially to the variance. For historical reference and for maintaining uniformity of testing on all the paper production lots, we have continued using the lysed-cell procedure (Figure 4). We also measure performance with intact-cell preparations (Figures 3 and 5). For any lot of filter paper, the intact-cell evaluation studies were independently validated by comparison to data obtained from its lysed-cell evaluation. The published and standardized acceptable serum volumes per 1/8-inch disk are 1.30 ± 0.19 µL (mean value and 95% confidence interval [CI]) for lysed-cell blood and 1.54 ± 0.17 µL for intact-cell blood.[1] The mean serum volume per 1/8-inch disk for lysed-cell blood differs from that of intact-cell blood. The mean values and CIs are the filter-paper

Hugh Retires

F. Hugh Gardner, a chemist working on the NSQAP team, retired January 2, 2009. Hugh served four years in the US Air Force, Strategic Air Command; and in 1969, he earned his BS in chemistry from St. Augustine's College, Raleigh, North Carolina. In 1971, he began his career at CDC. Those many years ago, he started working in the Coronary Drug Project; and as time went by, he worked in Aspirin Myocardial Infarction Studies I & II, the Early Treatment Diabetic Retinopathy Study, and rounded out his 42-year career working in NSQAP hemoglobinopathy research. Hugh solved a sample-injector problem with the instrument that measured hemoglobin A1c; this reduced the backlog of unanalyzed specimens. He was a two-time president of the CDC/ATSDR Chapter of Blacks in Government. In 2007, he presented a seminar, An Overview: 2006 Blacks in Government, at the Division of Laboratory Sciences, NCEH. At the BIG National Training Conference, he presented a seminar on newborn screening. Last year Hugh's mother passed away; and as a way of honoring Hugh and his mother, the BIG chapter initiated the Minnie Gardner Scholarship Award. Money collected for that award was donated by Hugh to the high school oratorical contestants taking part in the BIG Chapter's Annual Oratorical Competition. Recently, Hugh was in charge of NSQAP's participation in CDC's Health Awareness Day, which included a presentation by Tera Mize of Save Babies Through Screening Foundation. NSQAP sends Hugh "Best Wishes" in his well-deserved retirement.

evaluation parameters published in the Clinical and Laboratory Standards Institute (CLSI), formerly NCCLS-approved standard.[1] The CDC mean value for intact-cell evaluations for all lots is within the 95% CI defined by CLSI but below the mean value indicated by the CLSI standard.[1] In 2006, the mean value and CI for the intact-cell measurements were examined and discussed during a routinely scheduled review period for revision of the LA4 standard. The CLSI committee retained the original values (not produced at CDC) for intact cells in the revised standard. The mean value and 95% CI for intact cells (Figures 3 and 5) are the values based on CDC data covering more than ten filter paper lots.

Filter paper lots used in the CDC production of QC and PT specimens distributed in 2008 were W051 and W071 of Grade 903. All filter paper lots were analyzed for agreement with the evaluation parameters according to the CLSI-approved standard.[1]

Each year, with the extensive cooperation of the manufacturers (Whatman Inc., Fairfield, NJ, and Ahlstrom Filtration LLC, Holly Springs, PA) of filter paper approved (cleared) by the Food and Drug Administration (FDA) for blood collection, we have routinely evaluated new lots and compared new lots with previous lots. The criteria for acceptable performance are the limits established in the CLSI standard.[1] A manufacturer also is expected to establish its own testing program using the CLSI standard and make available to the user its certification data for each distributed lot of paper. The independent evaluations by CDC are an impartial and voluntary service offered as a function of our QA program; they do not constitute preferential endorsement of any product.

The serum-absorbance volumes of 24 lots of Grade 903 filter paper (Whatman Inc.) determined from lysed RBCs and for 14 lots determined from intact RBCs, are shown in chronological order. For W081, the most recent production lot of Grade 903 filter paper, we found the mean serum-absorbance volume was 1.45 µL for a 1/8-inch disk for lysed-cell blood and 1.52 µL per 1/8-inch disk for intact-cell blood. Each mean value is within the acceptable range for the matrix used. Lot W081 was homogeneous. Our data for a production lot depends on the filter paper sample provided by the manufacturer as being representative of the entire production batch, i.e., statistically valid sampling.

In 2008, the FDA approved the filter paper, Grade 226, produced by Ahlstrom Filtration LLC (Holly Springs, PA) as a blood collection device. CDC evaluated the Grade 226 according to the criteria previously described.[1]

The serum-absorbance volumes for six lots of Grade 226 filter paper determined from intact RBCs are shown in chronological order. Data and plot are not currently available for the lysed-cell preparations on the Ahlstrom filter paper, only intact-cell data are shown. For 8040201, the most recent production lot of Grade 226 filter paper, we found the mean serum-absorbance volume was 1.60 µL for a 1/8-inch disk for intact-cell blood. Each mean value was within the acceptable range for the matrix used. Lot 8040201 was homogeneous.

SPECIMEN PREPARATION AND DATA HANDLING

Tables and figures show the enriched concentrations of PT specimens and QC lots as well as the summarized quantitative data. The total concentration of each specimen or lot equaled the sum of the enriched concentration and the endogenous concentration (nonenriched). For thyroxine (T_4) PT specimens, the CDC assayed values were reported because of differences in the blood sources used for DBS production. Some specimens were enriched above the endogenous T_4 concentration, and some were enriched with T_4 after T_4 depletion of the base serum. Except for biotinidase, GALT, and hemoglobins, all DBS specimens in the PT surveys and QC production lots were prepared from whole blood of 50% or 55% hematocrit. Purified analytes or natural donor blood, except for TSH, which used the Third International Reference Preparation (81/565), were used for all enrichments. For galactosemia, enrichments were made with galactose and galactose-1-phosphate so that both free galactose (galactose alone) and total galactose (free galactose plus galactose present as galactose-1-phosphate) could be measured. For biotinidase and GALT, individual donor blood from adults with these disorders was used with the hematocrit adjusted to 50%. CDC assayed values were used as expected values for T_4, immunoreactive trypsinogen (IRT), GALT, SUAC, C3DC, C5DC, C10:1, and C14:1. All reported analytic values outside the 99% CI were excluded from the summaries of quantitative results.

For obtaining data on the QC materials, we estimated the method response to endogenous materials by performing weighted linear regression analyses for mean-reported concentrations versus enriched concentrations. We then extrapolated the regression lines to the Y-axis (intercept) to obtain an estimate of the observed endogenous analyte concentration for each method category. These estimates are reliable when (1) enrichments are accurate, (2) the analytic method gives a linear response across the range of the measurements, and (3) the slopes for regression lines are approximately equal to one.

In 2008, we applied the laboratory-reported specific cutoff values, when available, to our PT grading algorithm for clinical assessments; if no cutoff was reported, we used the NSQAP-assigned working cutoff values based on the national mean value for this assessment.

MASS SPECTROMETRY WORKGROUP

NSQAP has established the Mass Spectrometry Workgroup to serve as a clearinghouse for MS/MS services and research for its participants. The workgroup is comprised of nine members tasked with providing NSQAP participants with QC and PT materials for amino acids, acylcarnitines, second-tier CAH testing, and LSDs. In addition, workgroup members are conducting research to expand NSQAP's analyte offerings in our MS/MS panels in order to include all primary and secondary biomarkers for the ACMG-recommended Uniform Panel for newborn screening programs.

Acylcarnitine QC panels shipped in January 2009 (lot numbers 865-868) now contain an additional acylcarnitine, 3-hydroxyisovalerylcarnitine (C5OH), primary marker for 3-hydroxy-3-methylglutaric aciduria (HMG) and secondary marker for other disorders. The C5OH standard was provided courtesy of Cambridge Isotope Laboratories (Andover, MA). In addition, we expect to evaluate the addition of hydroxypalmitoylcarnitine (C16OH), primary marker for long-chain L-3-hydroxyacyl-CoA dehydrogenase deficiency (LCHAD) and trifunctional protein deficiency (TFP).

In addition to C5OH, the workgroup is evaluating the addition of arginine to its amino acid panels. Arginine is a marker for arginase deficiency, and will be part of NSQAP's panel beginning in 2010.

The second-tier CAH PT program has expanded its list of analytes to include 21-deoxycortisol. The first shipment of PT materials containing the new analyte was sent to seven laboratories in January, 2009.

While separate amino acid and acylcarnitine panels have been traditionally offered by NSQAP, workgroup members are developing blood pools that contain amino acids and acylcarnitines together in a single blood spot. The creation of combined amino acids and acylcarnitine pools will result in decreased number of wells needed for QC analysis in a single analytical run.

Workgroup members are also working on the development of QC and PT materials for x-linked adrenoleukodystrophy (X-ALD). We are establishing in

our laboratory facilities the analytical method developed at Johns Hopkins University by the Moser Group, and the Moser group has kindly supplied NSQAP with materials for assay validation. Workgroup members welcome the opportunity to investigate new analytes and mass spectrometry-based methods to better serve the needs of our participants.

For more information about NSQAP's Mass Spectrometry Workgroup or any of its current projects, please contact Victor De Jesus at vdejesus@cdc.gov.

CUTOFFS

When reporting cutoff values, we requested the decision level for sorting test results reported as presumptive positive (outside limits) from results reported as negative (within limits). The reported cutoff values are summarized in Tables 1 and 2 for domestic and foreign laboratories. The values for mean (arithmetic average), median (middle value), and mode (most frequent value) are shown for each analyte. The mean cutoff values for domestic and foreign laboratories are similar except for 17-OHP, which is twice as high for domestic laboratories, and for IRT, which is 21% higher for domestic laboratories. The range (min/max) of cutoff values is large for TSH, 17-OHP, total galactose (Gal), IRT, C3, and C16 for both domestic and foreign laboratories. The mean and median cutoff values for the MS/MS amino acids are similar for domestic and foreign laboratories; however, the range is larger for foreign laboratories. Mean cutoff values for Phe, citrulline (Cit), C5, and C5DC are almost identical for domestic and foreign laboratories.

PROFICIENCY TESTING

All PT panels contained five blind-coded 75-µL or 100-µL DBS specimens. Specimens in the PT panels either contained endogenous levels or were enriched with predetermined levels of T_4, TSH, 17-OHP, Gal, Phe, leucine (Leu), methionine (Met), Tyr, valine (Val), Cit, and acylcarnitines (C3, C3DC, C4, C5, C5DC, C6, C8, C10, C10:1, C14, C14:1, C16). CF Mutation Detection panels were made from the blood of either an adult or an adolescent CF donor. Separate panels for

FIGURE 3. Ahlstrom Grade 226 Specimen Collection Paper Serum Volume by Lot Number - Intact Red Blood Cells

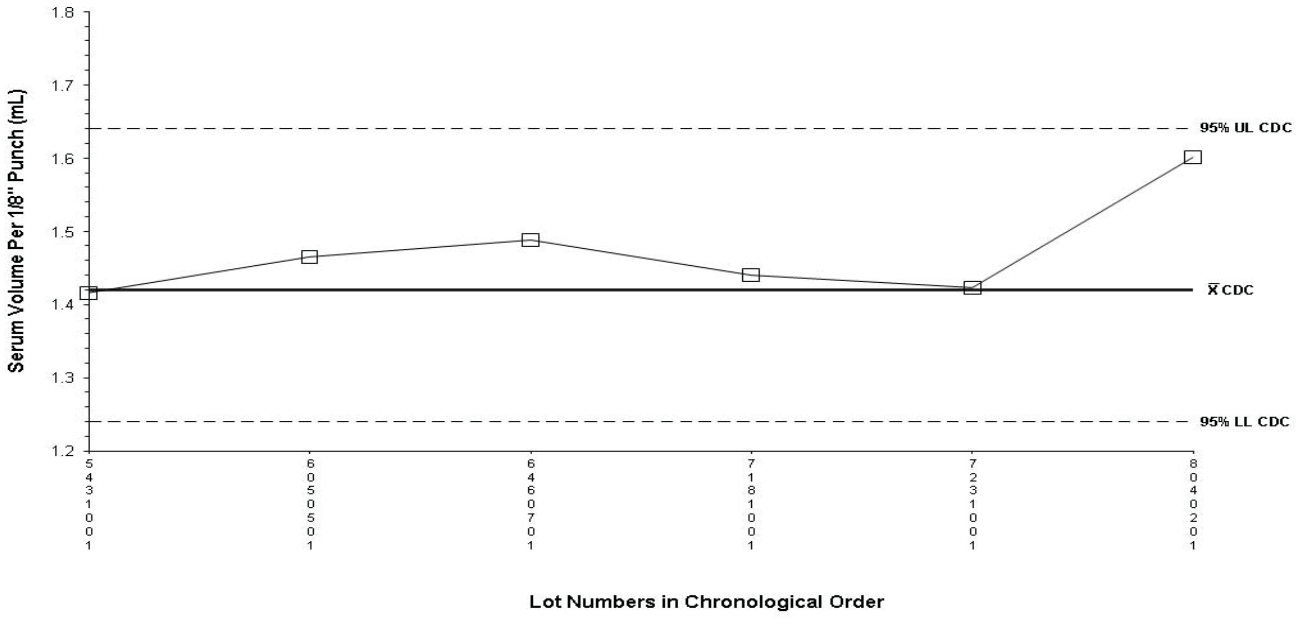
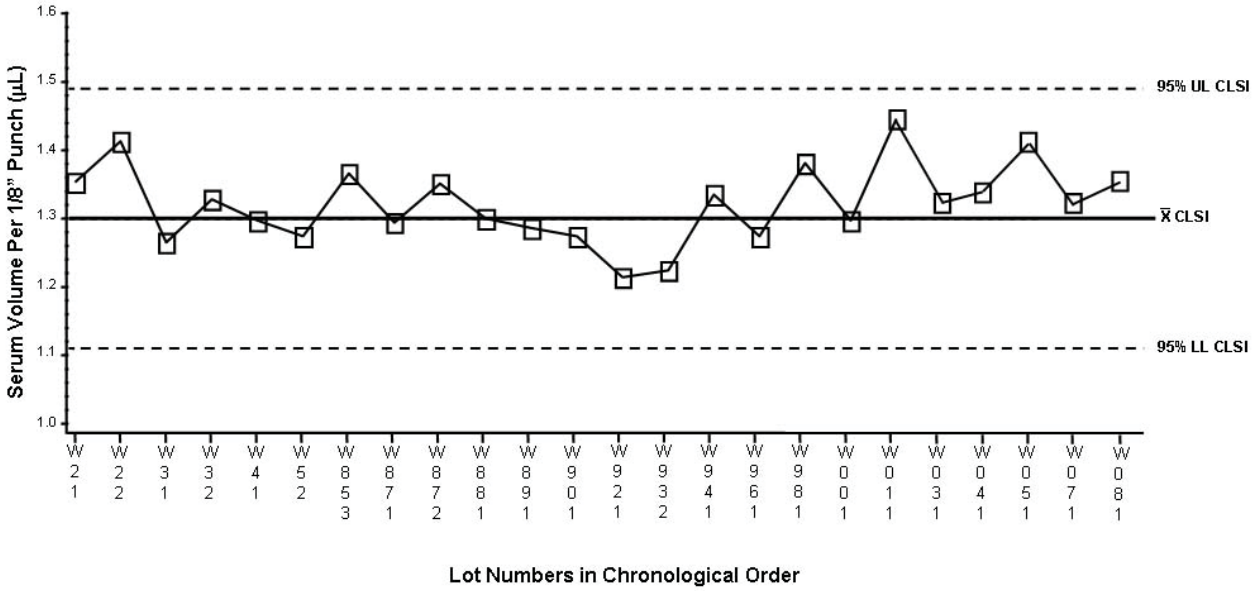


FIGURE 4. Whatman 903® Specimen Collection Paper
Serum Volume by Lot Number - Lysed Red Blood Cells



Whatman Inc.

FIGURE 5. Whatman 903® Specimen Collection Paper
Serum Volume by Lot Number - Intact Red Blood Cells

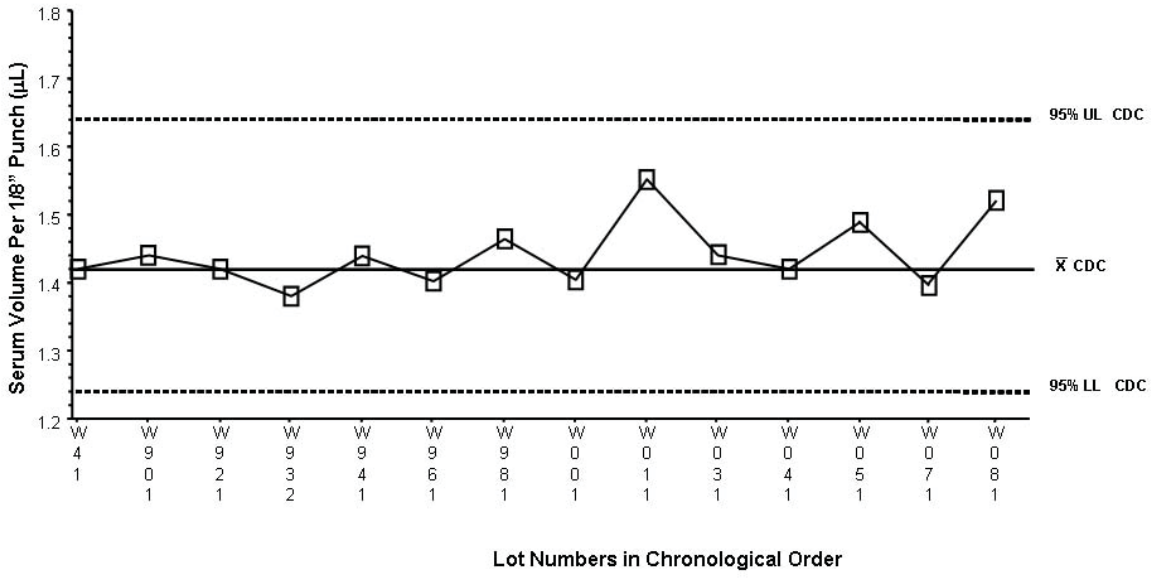


TABLE 1. 2008 Summary of Non-MS/MS Cutoff Values of Domestic and Foreign Laboratories

Domestic

Analyte	N	Mean	Median	Mode	Min/Max
T4	27	6.0	6.0	6.0	3.5-8.0
TSH	45	32.7	25.0	20.0	19.4-61.0
17-OHP	44	68.5	65.0	87.6	25-155
Galactose	23	11.3	10.0	10.0	5.6-20.0
Phenylalanine	12	2.7	2.5	2.0	2.0-4.0
Tyrosine	4	5.1	5.2	---	2.5-7.5
IRT	34	85.0	67.5	100.0	32-170
GALT	20	2.9	3.1	3.1	0.7-4.0

Foreign

Analyte	N	Mean	Median	Mode	Min/Max
T4	27	6.3	6.0	6.0	4.0-22.0
TSH	137	25.3	22.0	22.0	8.0-44.0
17-OHP	87	31.5	26.2	21.9	5.6-90.0
Galactose	72	11.6	10.0	10.0	4.0-30.0
Phenylalanine	54	2.9	3.0	3.0	1.7-4.0
Leucine	5	2.5	4.0	---	2.0-5.8
IRT	57	66.7	70.0	70.0	40-130
GALT	19	3.1	3.0	3.5	1.1-12.4

biotinidase deficiency and for GALT deficiency were prepared with purchased blood from donors with enzyme deficiencies. Specimens for the hemoglobinopathies panel were prepared from umbilical cord blood. Specimen sets were packaged in a zip-close metallized plastic bag with desiccant, instructions for analysis, and data-report forms for laboratories that did not report data by Internet. We prepared and distributed quarterly reports of all results that had been received by the deadline dates. In this annual report, the comparisons of results by different methods (Figures 7-31) are illustrated with the participants' reported PT data for one selected challenge for each analyte during the year. These are compared using bias plots that show the difference (positive or negative) by laboratory and method of the reported value subtracted from the expected value (CDC-measured endogenous level plus enrichment) and for T_4, IRT, GALT, Met, SUAC, C3DC, C5DC, C10:1, and C14:1, the reported value subtracted from the CDC assayed value. When examining the bias plots, note the scale-changes of the Y-axis relative to the expected value for each plot. A reported value matching the expected value will show the illustrated value as falling on the "0" line of the plot. A reasonable bias is less than ± 20% of the expected value or within 95% confidence interval (CI) for Figures 7-31. A summary of the specimen data for the selected-quarter PT challenge in 2008 is tabulated in the left margin for each figure.

The representative PT challenge specimens selected for the bias plots (Figures 7-31) were either above or below the cutoff value for the analyte. When comparing data scatter among figures, note that the scale (Y-axis) may differ. We included the 95% CI for the mean participant bias. Good performance of a method or group of methods is indicated by a tight scatter within this interval. In general, the quantitative comparisons (Figures 7-31) for PT challenges are reasonable within a method but vary among methods. The PT quantitative results are grouped by kit or method to illustrate any method-related differences in analyte recoveries. Because some of the pools in a routine PT survey represent a unique donor specimen, differences in endogenous materials in the donor specimens may influence method-related differences.

The scatter of values for T_4 (Figure 7) was different for some methods with either a large positive bias or consistently negative bias. The most pronounced difference was seen in the other methods category. The TSH and 17-OHP results (Figures 8 and 11) scattered consistently among the different methods, with several

TABLE 2. 2008 Summary of MS/MS Cutoff Values of Domestic and Foreign Laboratories

Domestic

Analyte	N	Mean	Median	Mode	Min/Max
Phenylalanine	46	2.5	2.3	2.3	1.6-4.0
Leucine	45	3.8	3.9	3.9	2.6-6.0
Methionine	44	1.3	1.3	1.5	0.8-2.0
Tyrosine	45	7.0	6.5	12.7	1.6-12.7
Valine	39	3.4	3.2	3.2	2.3-5.2
Citrulline	42	1.2	1.2	1.6	0.5-1.8
C3	46	5.98	6.20	6.50	1.20-8.70
C3DC	35	0.28	0.30	0.30	0.07-0.76
C4	44	1.45	1.41	1.80	0.44-2.14
C5	46	0.80	0.70	1.20	0.32-1.30
C5DC	46	0.28	0.30	0.35	0.09-0.53
C6	46	0.45	0.40	0.70	0.16-0.86
C8	25	0.50	0.50	0.50	0.25-1.00
C10	45	0.50	0.50	0.60	0.30-0.80
C10:1	42	0.36	0.35	0.45	0.15-0.56
C14	43	0.79	0.76	0.70	0.17-1.10
C14:1	44	0.62	0.65	0.80	0.20-0.89
C16	46	7.95	8.35	9.00	0.41-12.00

Foreign

Analyte	N	Mean	Median	Mode	Min/Max
Phenylalanine	112	2.5	2.3	2.5	1.0-6.6
Leucine	100	4.3	4.1	3.9	1.9-7.3
Methionine	95	1.0	0.9	0.8	0.4-2.8
Tyrosine	113	5.6	5.4	6.3	1.4-15.0
Valine	92	3.4	3.3	2.9	1.8-6.0
Citrulline	91	1.0	1.0	0.7	0.3-1.6
C3	104	6.18	6.00	5.00	3.00-10.50
C3DC	72	0.57	0.29	0.25	0.07-6.34
C4	100	1.19	1.07	1.00	0.50-3.00
C5	110	0.79	0.74	1.00	0.23-3.30
C5DC	134	0.28	0.21	0.20	0.10-1.70
C6	101	0.38	0.30	0.30	0.07-1.00
C8	114	0.41	0.40	0.50	0.13-1.05
C10	102	0.44	0.40	0.50	0.13-1.50
C10:1	91	0.32	0.28	0.40	0.10-1.00
C14	100	0.69	0.65	0.80	0.11-1.50
C14:1	98	0.50	0.45	0.40	0.05-1.67
C16	130	7.57	7.80	8.00	0.25-14.00

laboratories within a method showing some higher values for TSH and 17-OHP. For the predominately used TSH method, the values were reasonably consistent, more so than for the 17-OHP values for the most prevalent method used. For IRT (Figure 9), the reported results had a consistently positive bias. The recoveries were higher than expected for most participants. The CDC assayed (expected) value was within the lower 95% CL, which was calculated from participants' data and close to the participants' mean value. A different scatter is observed among the two most popular methods. The GALT quantitative data (Figure 10) appears reasonably distributed but the two methods appear to yield a different bias. Comparisons of values for Gal (Figure 12) showed that the scatter for one commonly used method differed markedly from the expected value and the other methods. This same difference in scatter among the two methods was also observed in 2007. For Phe (Figure 13), the

TABLE 3. 2008 Summary of Proficiency Testing Errors by Domestic and Foreign Laboratories

Domestic	Positive Specimens Assayed (N)	False-Negative Errors (%)	Negative Specimens Assayed (N)	False-Positive Errors (%)
Phenylketonuria	181	1.1	724	0.7
Maple Syrup Urine Disease (Leu)	142	0.0	568	0.7
Homocystinuria (Met)	139	0.0	556	0.0
Tyrosinemia I, II, III (Tyr)	152	3.3	608	0.0
Maple Syrup Urine Disease (Val)	122	0.0	488	0.4
Citrullinemia	134	0.0	536	0.2
C3 Screen	147	0.0	588	0.3
C3DC Screen	41	0.0	354	0.8
C4 Screen	139	0.0	556	1.1
C5 Screen	194	0.0	541	0.9
C5DC Screen	145	0.0	590	0.0
C6 Screen	143	0.0	572	0.3
C8 Screen	151	0.0	604	0.0
C10 Screen	142	0.0	568	0.4
C10:1 Screen	46	15.2	184	2.2
C14 Screen	184	0.0	501	0.0
C14:1 Screen	51	0.0	439	0.7
C16 Screen	146	0.0	584	0.0
Hypothyroidism	225	0.0	450	0.0
Congenital Adrenal Hyperplasia	221	0.0	444	0.2
Galactosemia	184	0.0	161	0.0
Biotinidase Deficiency	163	0.0	447	0.2
GALT Deficiency	129	0.0	516	0.0
Cystic Fibrosis (IRT)	80	1.3	120	3.3
Tyrosinemia I (SUAC)	24	0.0	16	12.5

Foreign	Positive Specimens Assayed (N)	False-Negative Errors (%)	Negative Specimens Assayed (N)	False-Positive Errors (%)
Phenylketonuria	546	0.7	2184	2.1
Maple Syrup Urine Disease (Leu)	331	0.3	1324	0.8
Homocystinuria (Met)	305	1.3	1220	0.2
Tyrosinemia I, II, III (Tyr)	356	1.1	1424	0.1
Maple Syrup Urine Disease (Val)	290	0.7	1160	0.3
Citrullinemia	283	2.1	1132	0.4
C3 Screen	333	1.2	1332	1.3
C3DC Screen	86	10.5	719	5.0
C4 Screen	324	1.2	1296	3.3
C5 Screen	464	0.9	1286	1.7
C5DC Screen	333	0.9	1372	0.9
C6 Screen	329	1.2	1316	1.1
C8 Screen	359	0.6	1436	0.8
C10 Screen	332	1.5	1328	1.7
C10:1 Screen	111	6.3	444	3.8
C14 Screen	443	0.7	1187	0.9
C14:1 Screen	121	1.7	989	0.8
C16 Screen	333	1.8	1332	0.4
Hypothyroidism	751	0.3	1539	1.2
Congenital Adrenal Hyperplasia	436	1.1	894	0.6
Galactosemia	556	0.5	504	0.6
Biotinidase Deficiency	207	0.0	568	1.8
GALT Deficiency	115	2.6	460	2.0
Cystic Fibrosis (IRT)	136	2.2	204	3.4
Tyrosinemia I (SUAC)	69	8.7	46	8.7

reported results showed reasonable variability within and among methods and a small population mean bias. Note the values obtained by users of the bacterial inhibition and other non-MS/MS methods were similar in scatter and bias to the MS/MS methods. The values reported for Leu (Figure 14) showed reasonable variability with a small population mean bias. The non-derivatized non-kit and non-derivatized kit MS/MS methods showed similar high bias and differed from the derivatized methods, in general. Methods for Met (Figure 15) produced reasonable scatter of values with all methods showing a consistently negative bias. Note the small scale on the Y-axis used to show differences among participants and methods. One of the commonly used Met methods showed a positive variance scatter relative to the other method. The overall participant mean value (3.1 mg/dL) was in close agreement with the CDC assayed value (3.4 mg/dL). For Tyr (Figure 16), all methods showed a reasonable scatter of values. The participants' mean value and the scatter of values demonstrated a general negative bias among all reported data. The reported data for Val (Figure 17) showed good agreement with the expected value and good agreement among methods. For Cit (Figure 18), of the two predominately used methods, one showed a negative bias and one a positive bias similar to the data presented in the 2006 and 2007 reports. A marked difference was observed for the derivatized non-kit and kit MS/MS methods. The reported data for SUAC (Figure 19) illustrates a wide scatter and mostly a positive bias among methods. Most SUAC values showed good recoveries relative to the expected value.

TABLE 4. 2008 Summary of Proficiency Testing Errors for Hemoglobinopathies by Domestic and Foreign Laboratories

Hemoglobinopathies	Domestic	Foreign
Specimens assayed	748	375
Phenotype errors	0.0%	0.01%
Clinical assessment errors	0.0%	0.01%

Overall, there were 2 phenotype errors in 2008, one FS and one FAC.

Representative bias plots are shown for all acylcarnitines in the PT challenges. Enrichments made with purchased acylcarnitines are based on weighed quantities. Slight variance in enrichments and recoveries may be attributed to impurities in the purchased materials and endogenous analyte concentrations. Reported values for C3, C4, C5 and C6 (Figures 20, 22, 23, and 25) showed reasonable scatter about the expected value while the reported values for one C6 (Figure 25) method showed a consistently negative clustered bias. The reported values for C3DC (Figure 21) and C5DC (Figure 24) illustrated a tightly clustered scatter of values; however, two methods (kit and non-kit) for each analyte showed markedly clustered differences in opposite directions. NOTE: These same clustered differences for the two methods were observed also with Cit (Figure 18). The users of derivatized non-kit and kit MS/MS methods, with tight scatters within a method group, reported very different values. For C8 (Figure 26), the reported values demonstrate a tight scatter around the expected value for all methods and the participants' mean value was in close agreement to the expected value. For C10 (Figure 27) and C10:1 (Figure 28), the reported values showed reasonable

TABLE 5. Genotype Analysis of Cystic Fibrosis Mutation Detection Specimens in 2008

	Specimens Assayed (N)	Correct Results	Incorrect Results	Not Evaluated*	Sample Failure
Quarter 1	140	97%	3%	23%	0%
Quarter 2	145	97%	3%	14%	0%
Quarter 3	165	97%	3%	13%	0%
Quarter 4	185	96%	4%	5%	2%
Total	635	97%	3%	13%	0.6%

* If one or both mutations are not part of the laboratory's panel, the specimen is not evaluated.

TABLE 6. Hemoglobin Phenotype Challenges Distributed in 2008

Phenotype	N
FA	3
FS	2
FAC	4
FAS	6
FSC	0

scatter among all laboratories and methods; however, a negative method bias was noted between the derivatized non-kit and kit methods. These clustered differences are similar to the MS/MS kit method differences observed for C3DC, C5DC, and Cit but in a negative direction. For C14 (Figure 29) and C14:1 (Figure 30), all methods showed reasonable scatter except for one C14 method that showed a negatively clustered bias. C16 (Figure 31) data demonstrated a tight cluster of values and most user laboratories showed a small negative bias.

Table 3 shows the proficiency testing errors reported by disorder in 2008 for all qualitative assessments by domestic laboratories and by foreign laboratories. We applied the laboratory-reported specific cutoff values to our grading algorithm for clinical assessments (Figure 6). Presumptive clinical classifications (qualitative assessments) of some specimens may differ by participant because of specific clinical assessment practices. If participants provided us with their cutoff values, we applied these cutoffs in our final appraisal of the error judgment. We based the rates for false-positive misclassifications on the number of distributed negative specimens and the rates for false-negative misclassifications on the number of positive specimens. False-positive misclassifications, which are a cost-benefit issue and a credibility factor for follow-up programs, should be monitored and kept as low as possible. Many of the misclassifications were in the false-positive category, with false-positive rates ranging from 0% to 12.5%. For domestic laboratories, the rate was 0.4% or lower for 16 of 25 biomarkers or disorders; and for foreign laboratories, the rate was 0.9% or lower for 12 of 25 biomarkers or disorders. Screening programs are designed to avoid false-negative reports; this precautionary design, however, contributes to false-positive reports and may cause many of the false-positive misclassifications. For domestic participants, the false-negative rate, expected to be zero, ranged from 0% to 15.2%. For foreign participants, false-negative classifications were reported for all biomarkers or disorders except biotinidase deficiency. For 21 biomarkers or disorders, no false-negative errors were reported for the domestic laboratories. A few of our PT specimens fell close to the decision level for classifications and thus rigorously tested the ability of laboratories to make the expected cutoff decision. Most specimens near the mean cutoff value are distributed as not-evaluated specimens and are not included in Table 3. Participants' data for these specimens are used to examine the relative analytical performance of the assays.

Table 4 shows the performance errors for hemoglobinopathies. The percentage of errors for qualitative assessments for sickle cell disease and other hemoglobinopathies was very small at 0.01% of the PT challenges. Overall there were only two errors for reported data for 2008. Like last year, the classification errors were the same for phenotype and clinical assessments within the domestic and foreign laboratory groups. Table 6 shows the phenotype challenges that were distributed in 2008 for hemoglobinopathies.

For errors detected in the PT program for 2008, reporting of a low quantitative value was the most frequent explanation among the common reasons given for false-negative errors reported by domestic participants.

Filter paper lots used in the CDC production of QC and PT specimens distributed in 2008 were W051 and W071 of Grade 903.

QUALITY CONTROL

For QC shipments of T_4, TSH, 17-OHP, IRT, Gal, amino acids (Phe, Leu, Met, Tyr, Val, Cit), and acylcarnitines (C0, C2, C3, C3DC, C4, C5, C5DC, C6, C8, C10, C14, C16, C18), each lot within a set contained a different analyte concentration. To ensure that a laboratory received representative sheets of the production batch, we used a randomizing system to select the set of sheets from the production batch for each laboratory. The QC materials were distributed semiannually. They included the DBS sheets, instructions for storage and analysis, and

data-report forms. Data from five analytic runs of each lot and shipment were compiled in the midyear and annual summary reports distributed to each participant. Intervals between runs were not the same for all laboratories because each participant's reported data cover a different time span.

The reported QC data are summarized in Tables 7a–7x, which show the analyte by series of QC lots, the number of measurements (N), the mean values, and the within-laboratory and total standard deviations (SD) by kit or analytic method. In addition, we used a weighted linear regression analysis to examine the comparability by method of reported versus enriched concentrations. Linear regressions (Y-intercept and slope) were calculated by method for all analytic values within an analyte QC series. Values outside the 99% CI (outliers) were excluded from the calculations.

Tables 7a-7x provide data about method-related differences in analytic recoveries and method bias. Because we prepared each QC lot series from one batch of hematocrit-adjusted, nonenriched blood, the endogenous concentration was the same for all specimens in a lot series. We calculated the within-laboratory SD component of the total SD and used the reported QC data from multiple analytic runs for regression analyses. We calculated the Y-intercept and slope in each table using all analyte concentrations within a lot series (e.g., lots 811, 812, 813). Because only three or four concentrations of QC materials are available for each analyte, a bias error in any one pool can markedly influence the slope and intercept. The Y-intercept provides one measure of the endogenous concentration level for an analyte. For Phe, Leu, Met, Tyr, Val, and Cit, participants also measured the endogenous concentrations by analyzing the nonenriched QC lots; the Y-intercepts and measured endogenous levels for these analytes were similar for most methods. Ideally, the slope should be 1.0, and most slopes were close to this value; however, the range was 0.6 to 4.3 because of a few methods and analytes.

Slope deviations may be related to analytic (dose-response) ranges for calibration curves or to poor recoveries for one or more specimens in a three- or four-specimen QC set. Because the endogenous concentration was the same for all QC lots within a series, it should not affect the slope of the regression line among methods. Generally, slope values substantially different from 1.0 indicate a method has an analytic bias.

REFERENCES

1. CLSI. Blood collection on filter paper for newborn screening programs; Approved standard–Fifth edition. CLSI document LA4-A5. Wayne, PA: Clinical and Laboratory Standards Institute; 2007.

FIGURE 6. EXPLANATION OF NSQAP GRADING ALGORITHM

Part 1.
The expected clinical assessment (EA) for a proficiency testing (PT) specimen is determined by comparing the expected value (EV), which is the sum of endogenous and enrichment values, with the CDC cutoff. The production of a PT specimen is designed so that the 99% confidence interval (CI) for the expected value (EV) of a positive specimen falls above the CDC cutoff, and the 99% CI for the expected value (EV) of a negative specimen falls below the CDC cutoff. Specimens that do not meet this 99% CI criterion are declared not-gradable/not-evaluated (NE).

Part 2.
When your reported clinical assessment (RA) differs from the expected clinical assessment (EA), the expected value (EV) is compared with the cutoff that you provide. This determines what your laboratory expected clinical assessment (LA) should be. If the expected clinical assessment (EA) and the laboratory expected clinical assessment (LA) are the same, but different from your reported clinical assessment (RA), your grade is either false-negative or false-positive. If the expected clinical assessment (EA) and the laboratory expected clinical assessment (LA) are not the same, your reported clinical assessment (RA) will not be graded as incorrect because of a significant difference between the CDC cutoff and your cutoff (see examples below). If you do not provide a cutoff, your laboratory expected clinical assessment (LA) cannot be determined; and your grade will be based on the CDC cutoff.

Part 3.
NSQAP's determination of a final clinical assessment for a specimen is based on the Clinical Laboratory Improvement Amendments (CLIA) regulations (http://www.phppo.cdc.gov/clia/regs/subpart_i.aspx#493.929), whereby the PT provider "must compare the laboratory's response for each analyte with the response that reflects agreement of either 80% of ten or more referee laboratories or 80% or more of all participating laboratories." A NSQAP gradable specimen must have 80% or more agreement among domestic laboratories. A specimen with less than 80% agreement is not-gradable/not-evaluated (NE).

Examples of Grading Scenarios

Analyte	CDC Cutoff	Expected Value (EV)	Lab Cutoff	Assessment: (EA) EV/CDC cutoff	Assessment: (LA) EV/Lab cutoff	Assessment: (RA) Lab reported	Lab Grade
TSH	25	13	30	Neg	Neg	Pos	FP
TSH	25	13	10	Neg	Pos	Pos	CD
Leu	4.1	6.7	4.5	Pos	Pos	Neg	FN
Leu	4.1	6.7	8.0	Pos	Neg	Neg	CD

FN = False negative
FP = False positive
CD = Cutoff Difference - clinical assessment is not judged as incorrect

TSH = Thyroid-stimulating Hormone
Leu = Leucine

Note that the grade is based on the reported clinical assessment, not on the reported value. Overall Statistics, which are generated from all participants' data, and Mean Reported Concentrations by method are provided on the Web site for analytical reference only.

FIGURE 7-8. Reproducibility of Results by Different Methods – Thyroxine and Thyroid-Stimulating Hormone

Figure 7. Bias Plot of Thyroxine Values by Method
Quarter 1, Specimen 3
Assayed Value (AV)[4] 7.8 µg/dL serum

Quarter 1	
Specimen 3	
CDC Assayed	7.8
Participant Mean	7.2
Participant Bias[3]	-0.6

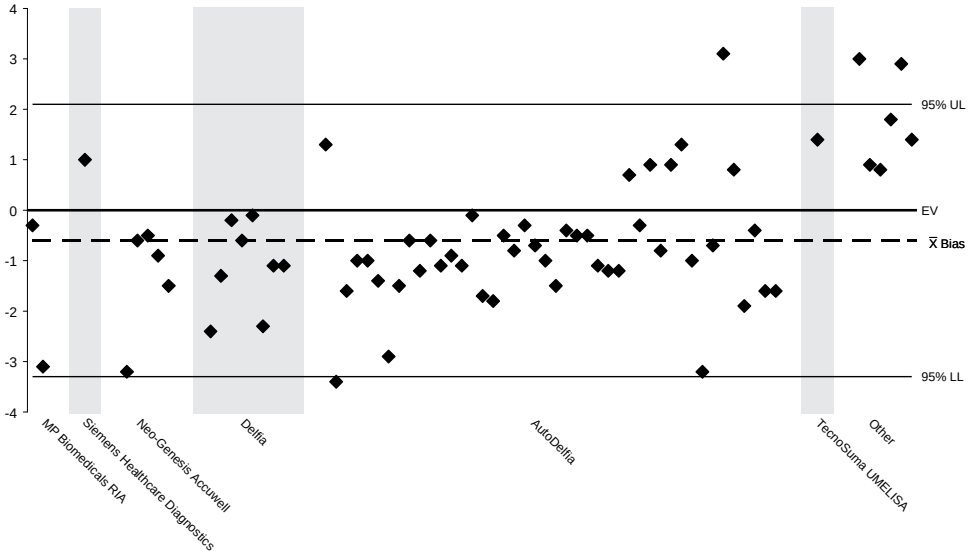
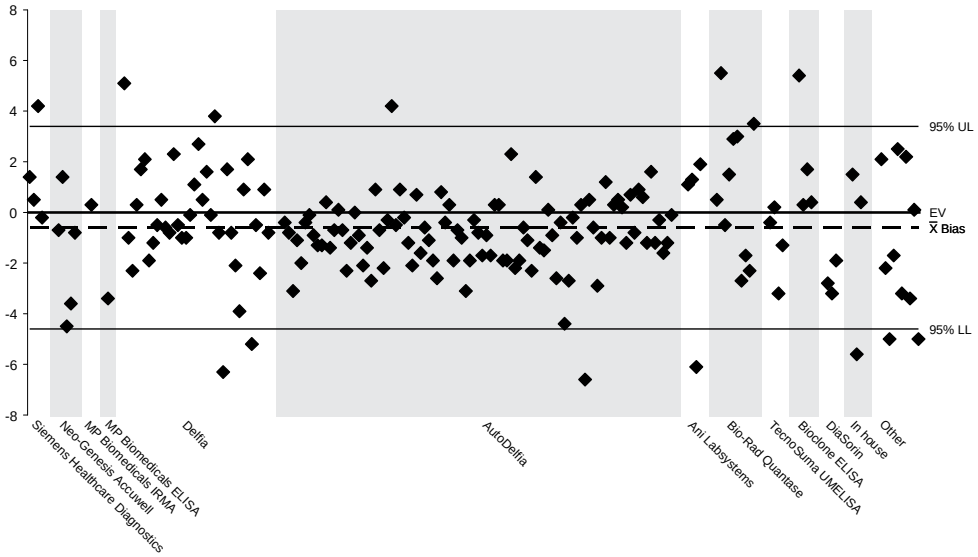


Figure 8. Bias Plot of Thyroid-Stimulating Hormone Values by Method
Quarter 3, Specimen 4
Expected Value (EV)[1] 10.7 µIU/mL serum

Quarter 3	
Specimen 4	
Enriched	9.0
CDC Assayed	11.7
Participant Mean	10.1
CDC Bias[2]	1.0
Participant Bias[3]	-0.6



[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]± CDC bias is the CDC assayed value minus EV.
[3]± Participant bias ($\bar{X}$ Bias) is the Participant mean assayed value minus EV, represented by the broken line. Participant mean excludes outlier values.
[4]AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURE 9-10. Reproducibility of Results by Different Methods – Cystic Fibrosis (IRT) and Galactose-1-Phosphate Uridyltransferase (GALT)

Figure 9. Bias Plot of Cystic Fibrosis (IRT) Values by Method
Quarter 1, Specimen 1
Assayed Value (AV)[4] 101.2 ng/mL whole blood

Quarter 1	
Specimen 1	
CDC Assayed	101.2
Participant Mean	115.3
Participant Bias[3]	14.1

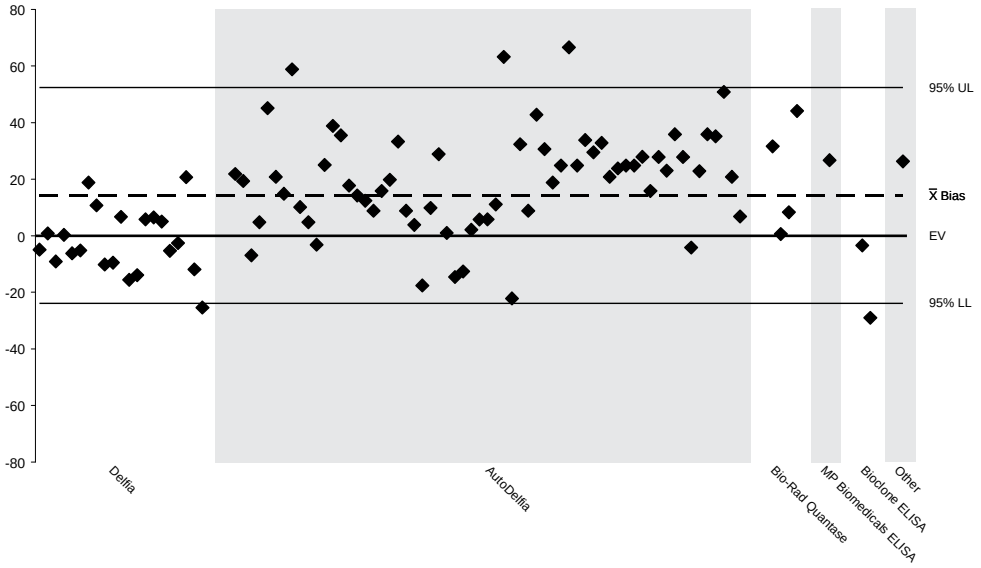
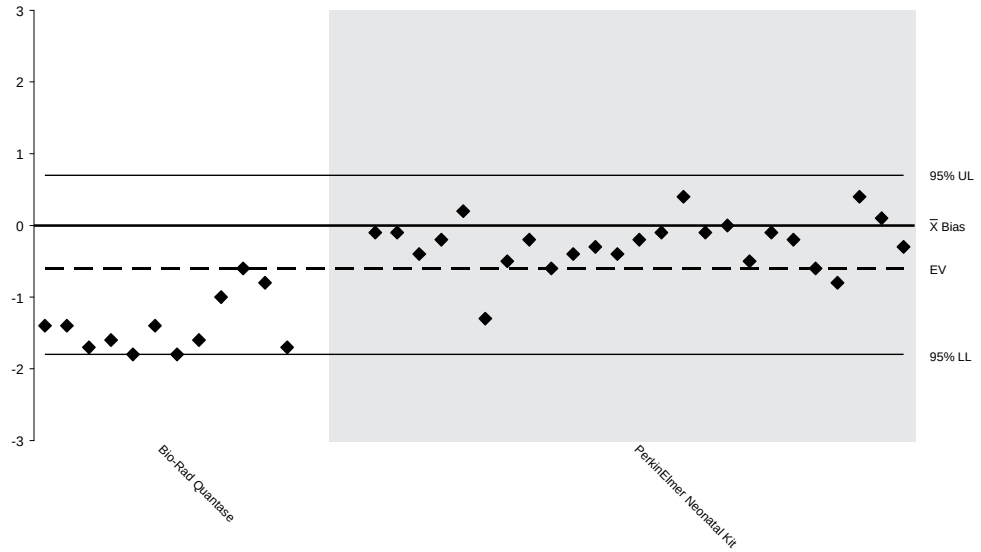


Figure 10. Bias Plot of Galactose-1-Phosphate Uridyltransferase (GALT) Values by Method
Quarter 1, Specimen 5
Assayed Value (AV)[4] 1.8 U/g Hb

Quarter 1	
Specimen 5	
CDC Assayed	1.8
Participant Mean	1.2
Participant Bias[3]	-0.6



[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]± CDC bias is the CDC assayed value minus EV.
[3]± Participant bias ($\bar{X}$ Bias) is the Participant mean assayed value minus EV, represented by the broken line. Participant mean excludes outlier values.
[4]AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURE 11-12. Reproducibility of Results by Different Methods – 17 α-Hydroxyprogesterone and Total Galactose

Figure 11. Bias Plot of 17 α-Hydroxyprogesterone Values by Method
Quarter 3, Specimen 4
Expected Value (EV)[1] 126 ng/mL serum

Quarter 3	
Specimen 4	
Enriched	125.0
CDC Assayed	116.8
Participant Mean	135.3
CDC Bias[2]	-9.2
Participant Bias[3]	9.3

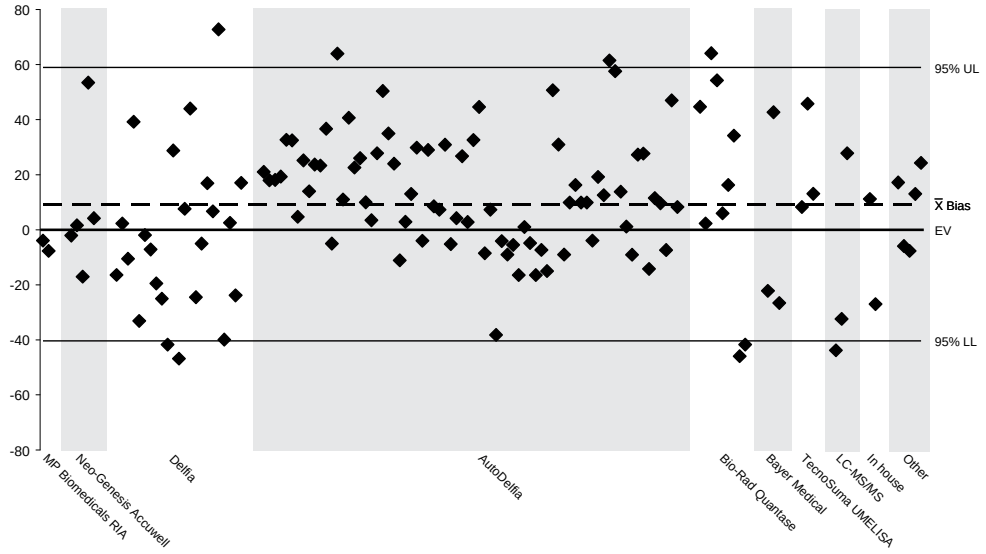
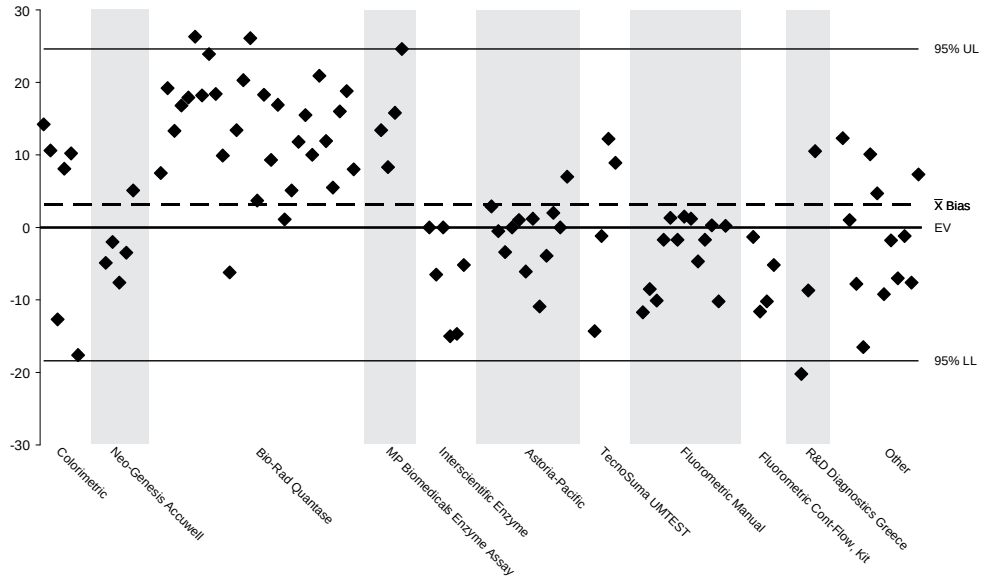


Figure 12. Bias Plot of Total Galactose Values by Method
Quarter 3, Specimen 4
Expected Value (EV)[1] 31.7 mg/dL whole blood

Quarter 3	
Specimen 4	
Enriched	30.0
CDC Assayed	30.8
Participant Mean	34.8
CDC Bias[2]	-0.9
Participant Bias[3]	3.1



[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]± CDC bias is the CDC assayed value minus EV.
[3]± Participant bias ($\bar{X}$ Bias) is the Participant mean assayed value minus EV, represented by the broken line. Participant mean excludes outlier values.

FIGURE 13-14. Reproducibility of Results by Different Methods – Phenylalanine and Leucine

Figure 13. Bias Plot of Phenylalanine Values by Method
Quarter 3, Specimen 3
Expected Value (EV)[1] 6.7 mg/dL whole blood

Quarter 3	
Specimen 3	
Enriched	6.0
CDC Assayed	6.4
Participant Mean	6.9
CDC Bias[2]	-0.3
Participant Bias[3]	0.2

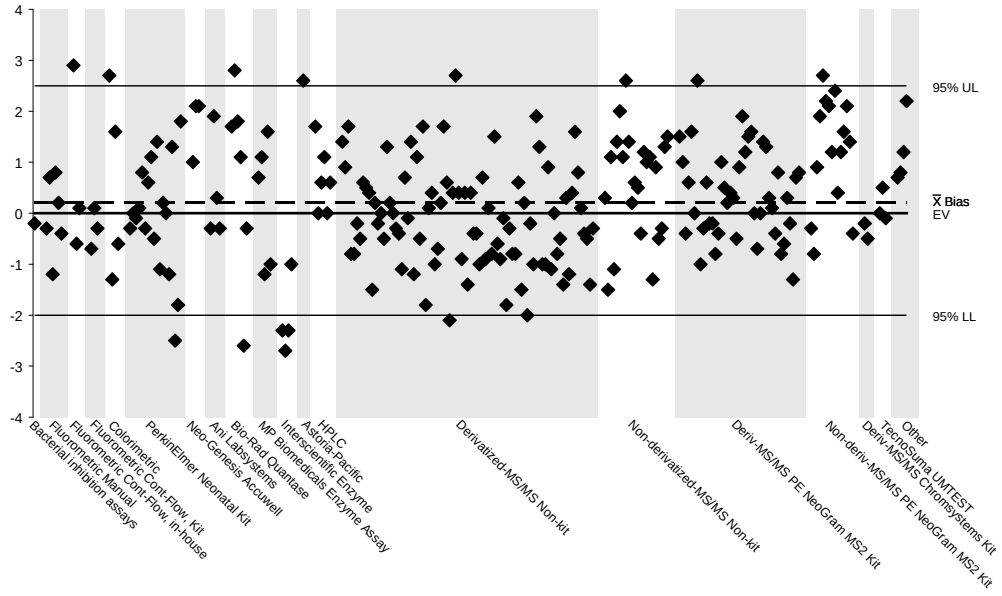
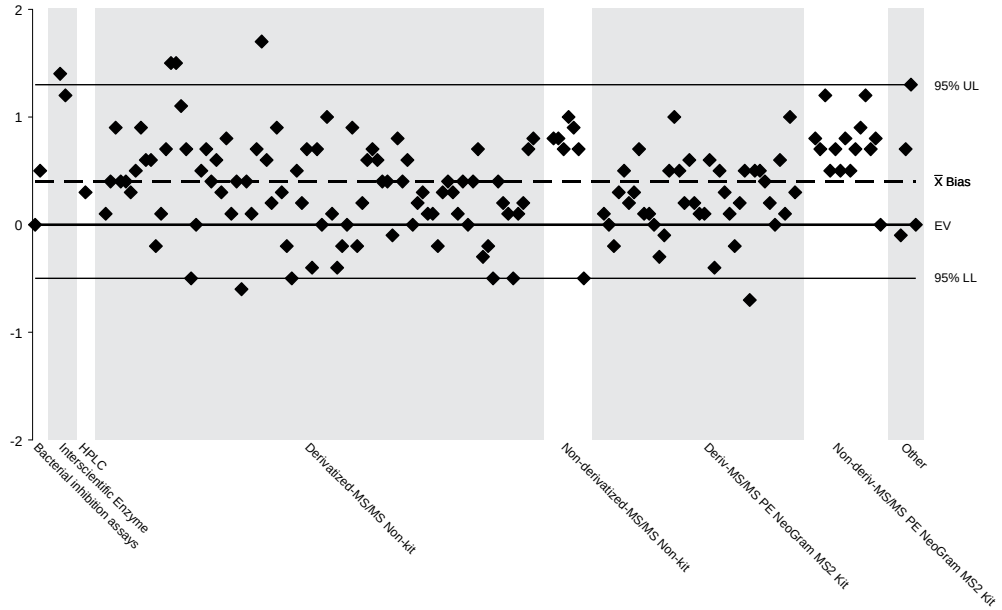


Figure 14. Bias Plot of Leucine Values by Method
Quarter 1, Specimen 5
Expected Value (EV)[1] 2.5 mg/dL whole blood

Quarter 1	
Specimen 5	
Enriched	0
CDC Assayed	2.4
Participant Mean	2.9
CDC Bias[2]	-0.1
Participant Bias[3]	0.4



[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]± CDC bias is the CDC assayed value minus EV.
[3]± Participant bias ($\bar{X}$ Bias) is the Participant mean assayed value minus EV, represented by the broken line. Participant mean excludes outlier values.

FIGURE 15-16. Reproducibility of Results by Different Methods – Methionine and Tyrosine

Figure 15. Bias Plot of Methionine Values by Method
Quarter 3, Specimen 4
Assayed Value (AV)[4] 3.4 mg/dL whole blood

Quarter 3	
Specimen 4	
CDC Assayed	3.4
Participant Mean	3.1
Participant Bias[3]	-0.3

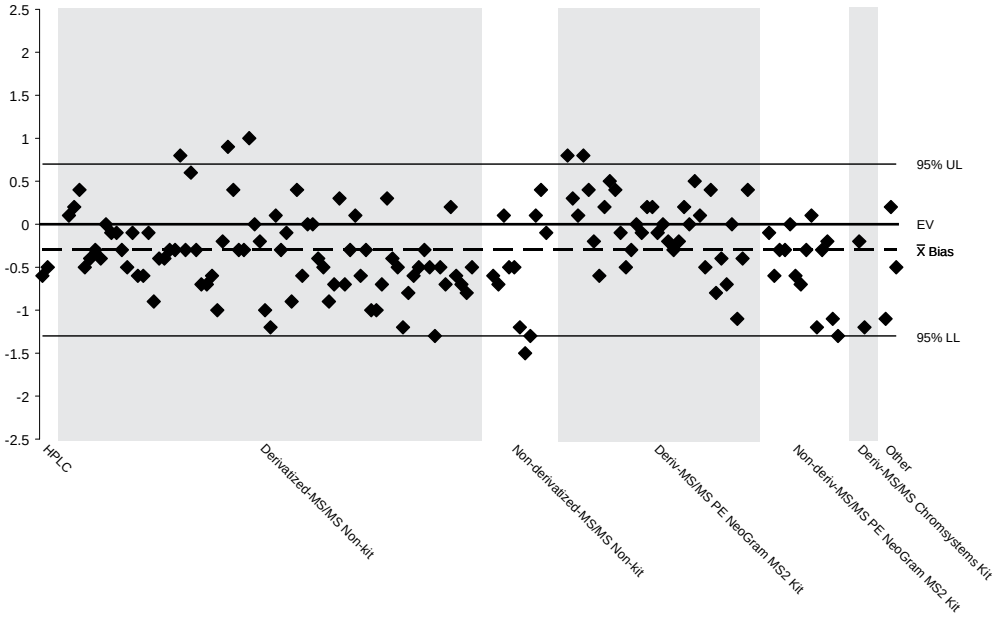
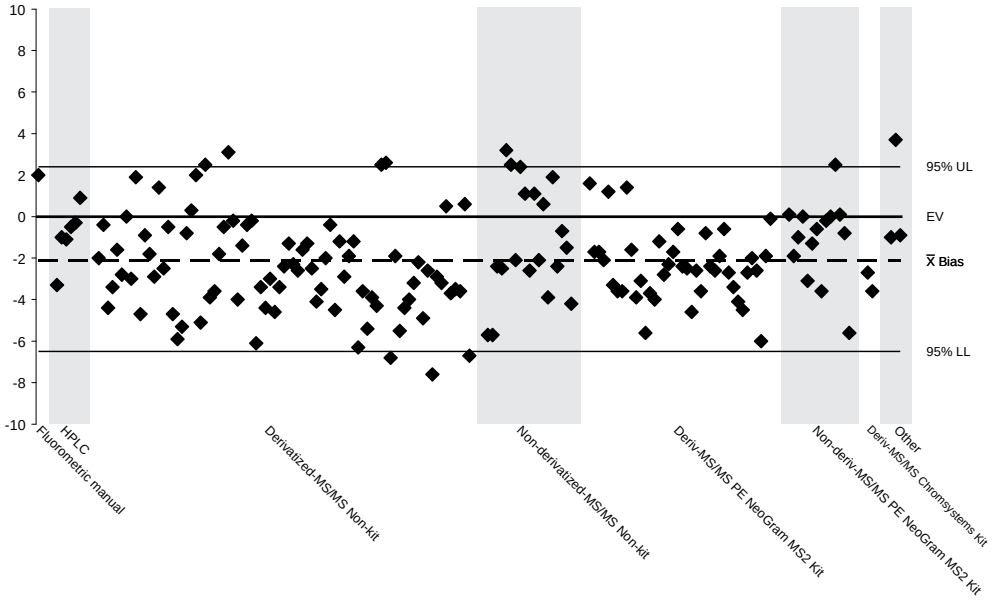


Figure 16. Bias Plot of Tyrosine Values by Method
Quarter 3, Specimen 5
Expected Value (EV)[1] 16.2 mg/dL whole blood

Quarter 3	
Specimen 5	
Enriched	15.0
CDC Assayed	14.7
Participant Mean	14.1
CDC Bias[2]	-1.5
Participant Bias[3]	-2.1



[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]± CDC bias is the CDC assayed value minus EV.
[3]± Participant bias ($\overline{X}$ Bias) is the Participant mean assayed value minus EV, represented by the broken line. Participant mean excludes outlier values.
[4]AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURE 17-18. Reproducibility of Results by Different Methods – Valine and Citrulline

Figure 17. Bias Plot of Valine Values by Method
Quarter 1, Specimen 4
Expected Value (EV)[1] 7.0 mg/dL whole blood

Quarter 1	
Specimen 4	
Enriched	5.5
CDC Assayed	5.6
Participant Mean	6.5
CDC Bias[2]	-1.4
Participant Bias[3]	-0.5

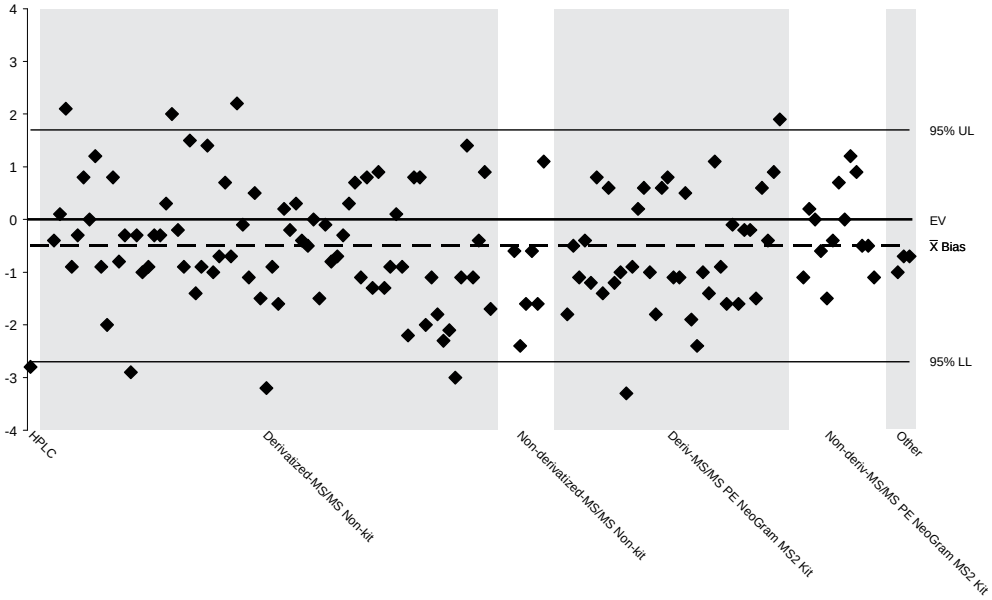
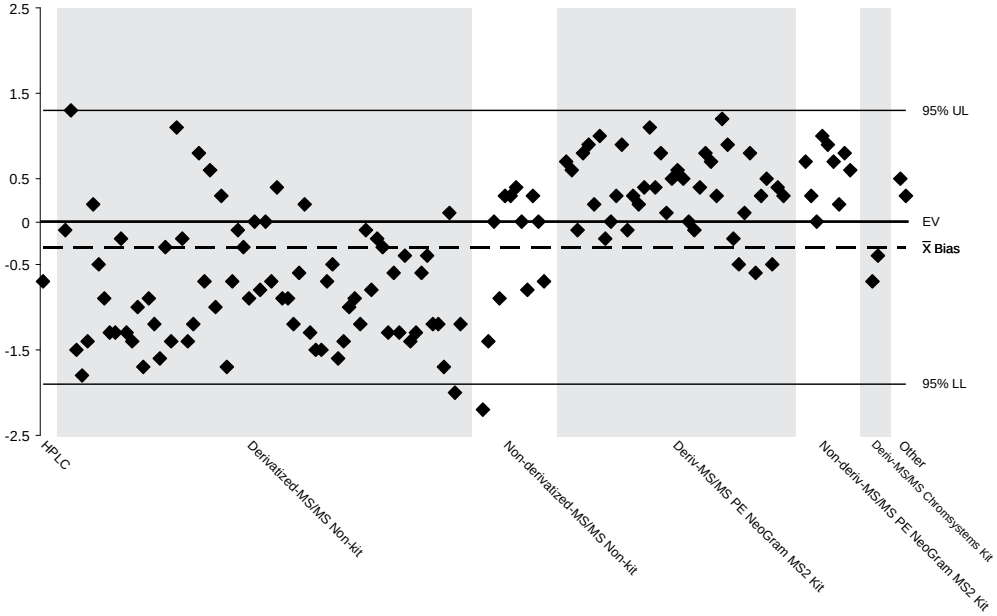


Figure 18. Bias Plot of Citrulline Values by Method
Quarter 3, Specimen 1
Expected Value (EV)[1] 3.9 mg/dL whole blood

Quarter 3	
Specimen 1	
Enriched	3.5
CDC Assayed	3.1
Participant Mean	3.6
CDC Bias[2]	-0.8
Participant Bias[3]	-0.3



[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]± CDC bias is the CDC assayed value minus EV.
[3]± Participant bias ($\bar{X}$ Bias) is the Participant mean assayed value minus EV, represented by the broken line. Participant mean excludes outlier values.

FIGURE 19-20. Reproducibility of Results by Different Methods – Succinylacetone (SUAC) and Propionylcarnitine (C3)

Figure 19. Bias Plot of Succinylacetone (SUAC) Values by Method
Quarter 4, Specimen 3
Assayed Value (AV)[4] 2.69 µmol/L whole blood

Quarter 4	
Specimen 3	
CDC Assayed	2.69
Participant Mean	3.95
Participant Bias[3]	1.26

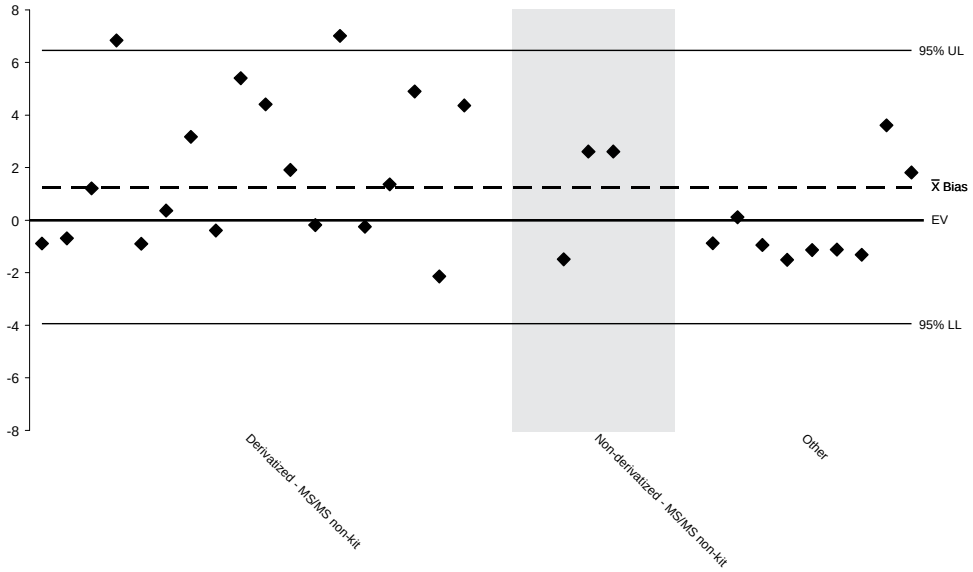
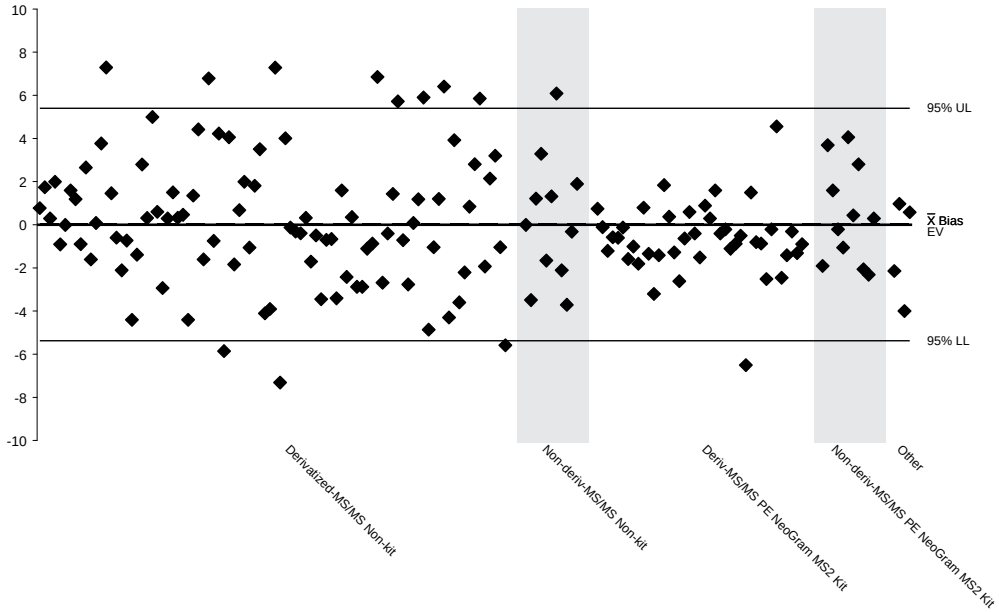


Figure 20. Bias Plot of Propionylcarnitine (C3) Values by Method
Quarter 1, Specimen 3
Expected Value (EV)[1] 14.41 µmol/L whole blood

Quarter 1	
Specimen 3	
Enriched	10.00
CDC Assayed	14.37
Participant Mean	14.42
CDC Bias[2]	-0.04
Participant Bias[3]	0.01



[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]± CDC bias is the CDC assayed value minus EV.
[3]± Participant bias ($\bar{X}$ Bias) is the Participant mean assayed value minus EV, represented by the broken line. Participant mean excludes outlier values.
[4]AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURE 21-22. Reproducibility of Results by Different Methods – Malonylcarnitine (C3DC) and Butyrylcarnitine (C4)

Figure 21. Bias Plot of Malonylcarnitine (C3DC) Values by Method
Quarter 1, Specimen 2
Assayed Value (AV)[4] 0.97 µmol/L whole blood

Quarter 1	
Specimen 2	
CDC Assayed	0.97
Participant Mean	1.40
Participant Bias[3]	0.43

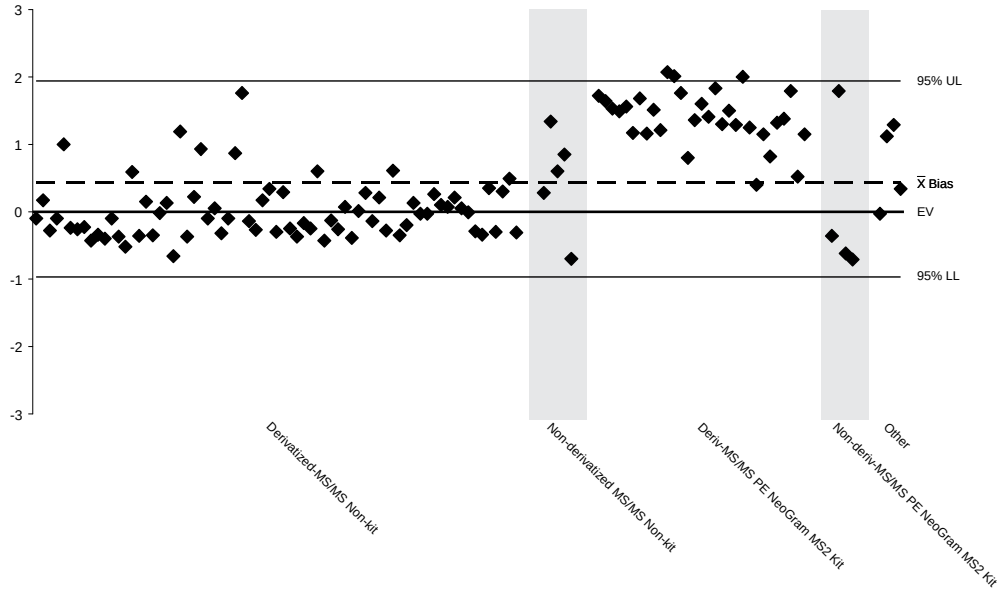
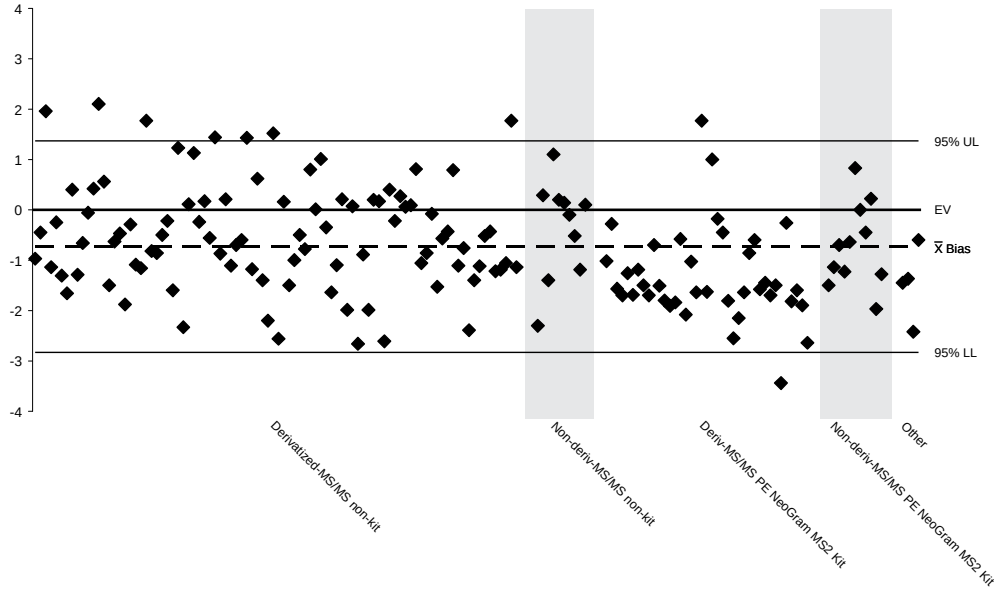


Figure 22. Bias Plot of Butyrylcarnitine (C4) Values by Method
Quarter 1, Specimen 2
Expected Value (EV)[1] 6.60 µmol/L whole blood

Quarter 1	
Specimen 2	
Enriched	6.00
CDC Assayed	6.55
Participant Mean	5.87
CDC Bias[2]	-0.05
Participant Bias[3]	-0.73



[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]± CDC bias is the CDC assayed value minus EV.
[3]± Participant bias ($\bar{X}$ Bias) is the Participant mean assayed value minus EV, represented by the broken line. Participant mean excludes outlier values.
[4]AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURE 23-24. Reproducibility of Results by Different Methods – Isovalerylcarnitine (C5) and Glutarylcarnitine (C5DC)

Figure 23. Bias Plot of Isovalerylcarnitine (C5) Values by Method
Quarter 1, Specimen 1
Expected Value (EV)[1] 2.63 µmol/L whole blood

Quarter 1	
Specimen 1	
Enriched	2.50
CDC Assayed	2.04
Participant Mean	2.26
CDC Bias[2]	-0.59
Participant Bias[3]	-0.37

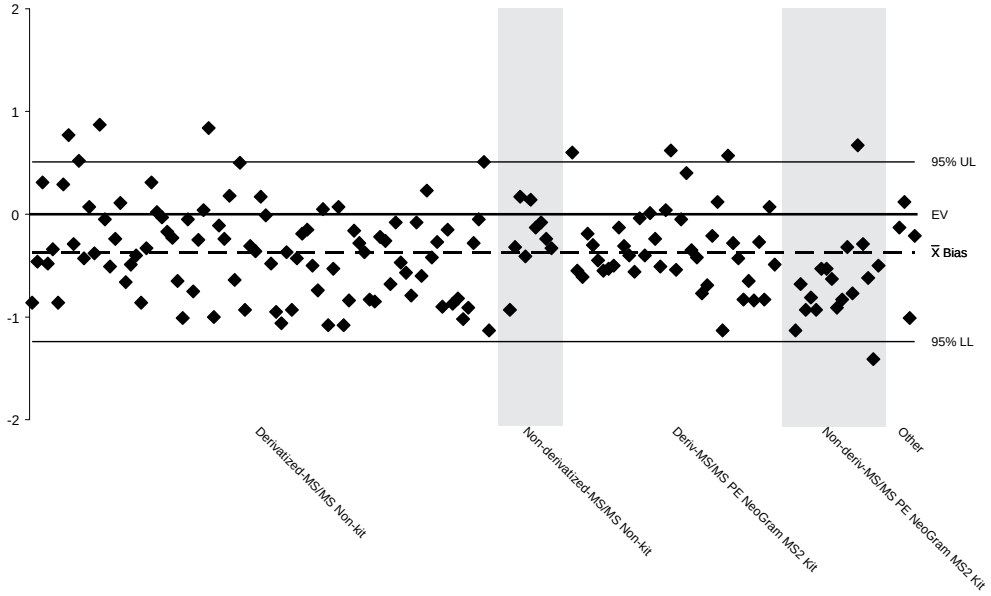
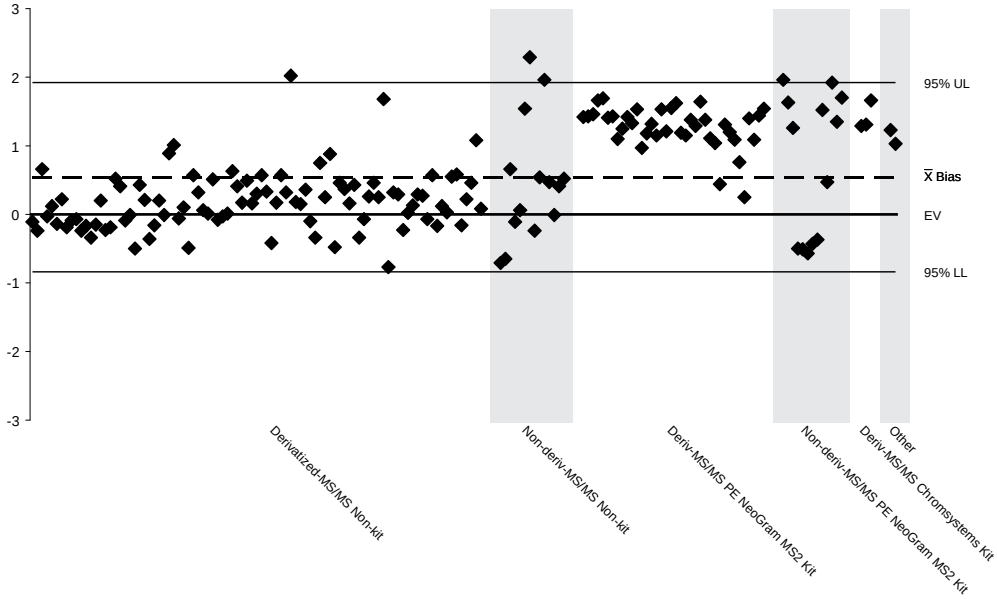


Figure 24. Bias Plot of Glutarylcarnitine (C5DC) Values by Method
Quarter 3, Specimen 4
Assayed Value (AV)[4] 0.84 µmol/L whole blood

Quarter 3	
Specimen 4	
CDC Assayed	0.84
Participant Mean	1.38
Participant Bias[3]	0.54



[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]± CDC bias is the CDC assayed value minus EV.
[3]± Participant bias ($\bar{X}$ Bias) is the Participant mean assayed value minus EV, represented by the broken line. Participant mean excludes outlier values.
[4]AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURE 25-26. Reproducibility of Results by Different Methods – Hexanoylcarnitine (C6) and Octanoylcarnitine (C8)

Figure 25. Bias Plot of Hexanoylcarnitine (C6) Values by Method
Quarter 3, Specimen 1
Expected Value (EV)[1] 2.55 µmol/L whole blood

Quarter 3	
Specimen 1	
Enriched	2.50
CDC Assayed	2.13
Participant Mean	2.43
CDC Bias[2]	-0.42
Participant Bias[3]	-0.12

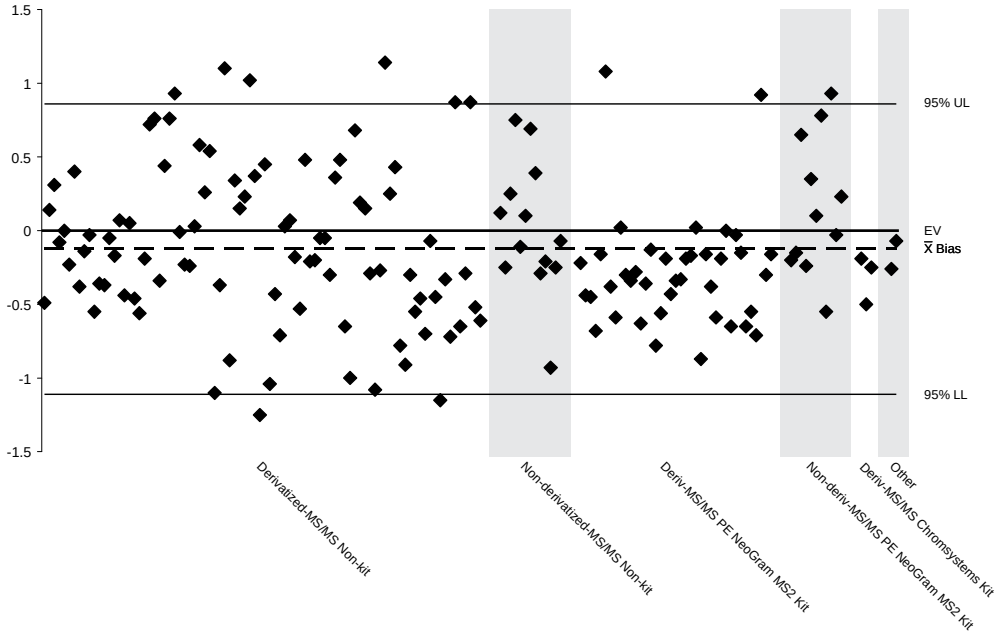
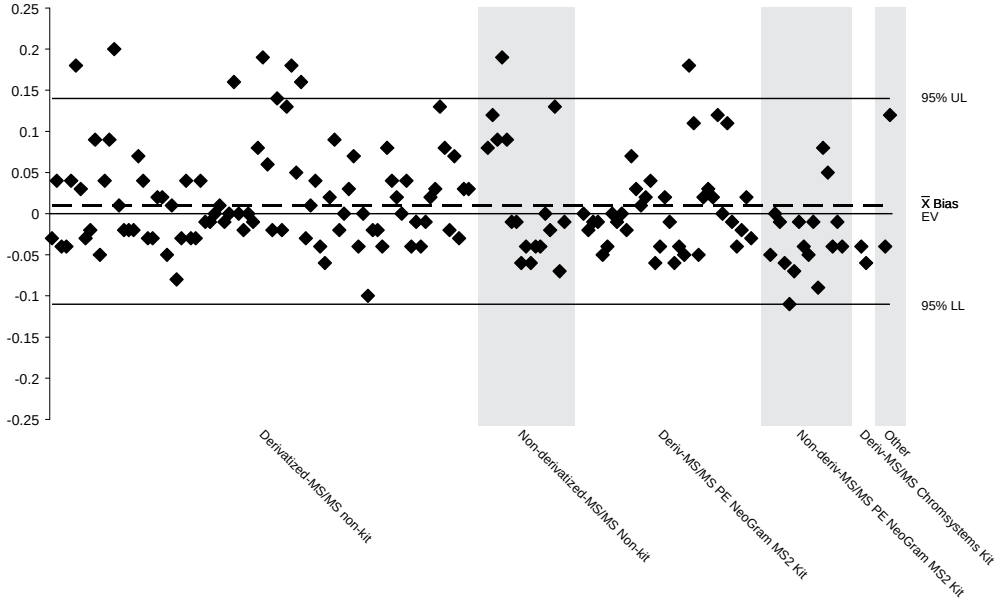


Figure 26. Bias Plot of Octanoylcarnitine (C8) Values by Method
Quarter 3, Specimen 2
Expected Value (EV)[1] 0.11 µmol/L whole blood

Quarter 3	
Specimen 2	
Enriched	0.00
CDC Assayed	0.10
Participant Mean	0.12
CDC Bias[2]	-0.01
Participant Bias[3]	0.01



[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]± CDC bias is the CDC assayed value minus EV.
[3]± Participant bias ($\bar{X}$ Bias) is the Participant mean assayed value minus EV, represented by the broken line. Participant mean excludes outlier values.

FIGURE 27-28. Reproducibility of Results by Different Methods – Decanoylcarnitine (C10) and Decenoylcarnitine (C10:1)

Figure 27. Bias Plot of Decanolycarnitine (C10) Values by Method
Quarter 1, Specimen 4
Expected Value (EV)[1] 2.11 µmol/L whole blood

Quarter 1	
Specimen 4	
Enriched	2.00
CDC Assayed	2.59
Participant Mean	2.04
CDC Bias[2]	0.48
Participant Bias[3]	-0.07

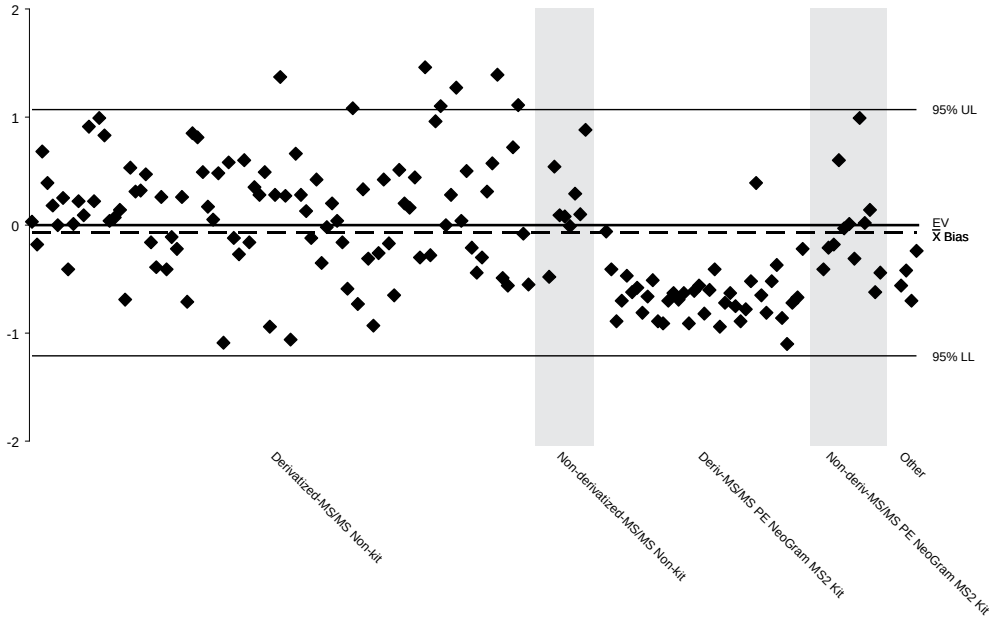
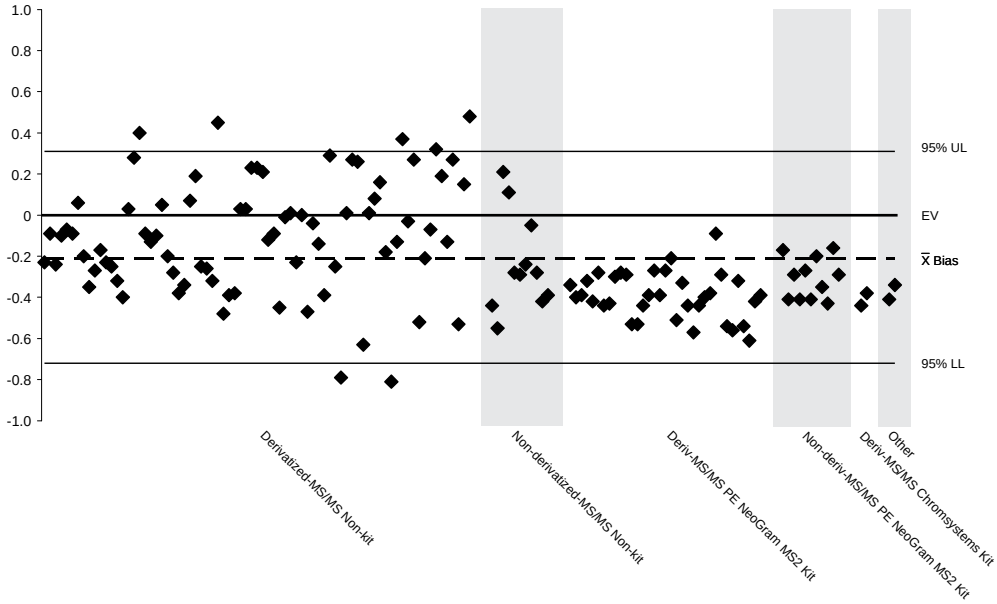


Figure 28. Bias Plot of Decenoylcarnitine (C10:1) Values by Method
Quarter 3, Specimen 1
Assayed Value (AV)[4] 0.99 µmol/L whole blood

Quarter 3	
Specimen 1	
CDC Assayed	0.99
Participant Mean	0.78
Participant Bias[3]	-0.21



[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]± CDC bias is the CDC assayed value minus EV.
[3]± Participant bias ($\overline{X}$ Bias) is the Participant mean assayed value minus EV, represented by the broken line. Participant mean excludes outlier values.
[4]AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURE 29-30. Reproducibility of Results by Different Methods – Myristoylcarnitine (C14) and Tetradecenoylcarnitine (C14:1)

Figure 29. Bias Plot of Myristoylcarnitine (C14) Values by Method
Quarter 3, Specimen 3
Expected Value (EV)[1] 5.13 µmol/L whole blood

Quarter 3	
Specimen 3	
Enriched	5.00
CDC Assayed	5.14
Participant Mean	4.65
CDC Bias[2]	0.01
Participant Bias[3]	-0.48

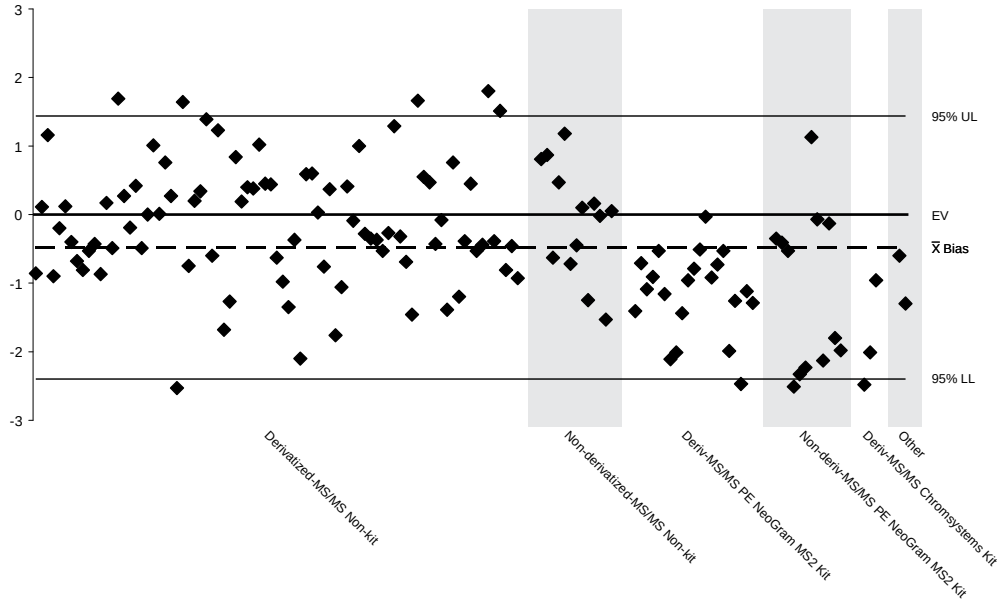
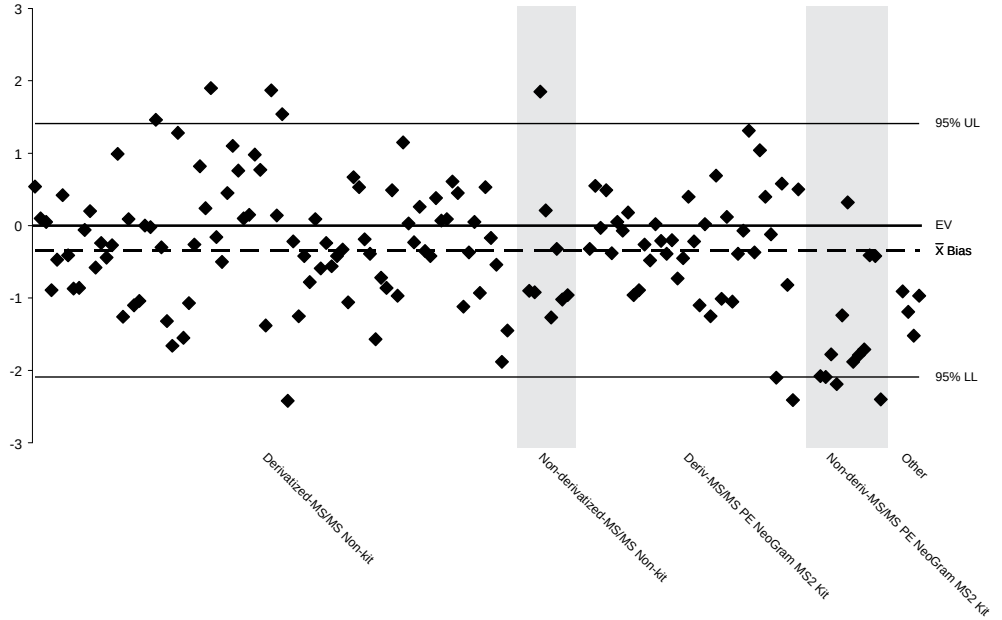


Figure 30. Bias Plot of Tetradecenoylcarnitine (C14:1) Values by Method
Quarter 1, Specimen 5
Assayed Value (AV)[4] 3.86 µmol/L whole blood

Quarter 1	
Specimen 5	
CDC Assayed	3.86
Participant Mean	3.52
Participant Bias[3]	-0.34

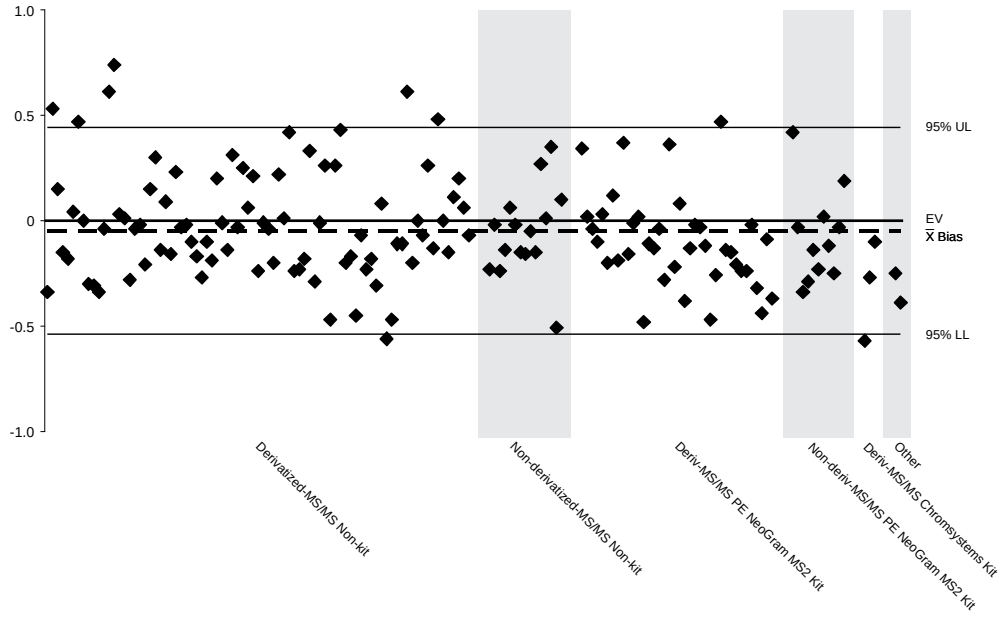


[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]± CDC bias is the CDC assayed value minus EV.
[3]± Participant bias ($\bar{X}$ Bias) is the Participant mean assayed value minus EV, represented by the broken line. Participant mean excludes outlier values.
[4]AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURE 31. Reproducibility of Results by Different Methods – Palmitoylcarnitine (C16)

Quarter 3	
Specimen 4	
Enriched	0.00
CDC Assayed	1.35
Participant Mean	1.29
CDC Bias[2]	0.01
Participant Bias[3]	-0.05

Figure 31. Bias Plot of Palmitoylcarnitine (C16) Values by Method
Quarter 3, Specimen 4
Expected Value (EV)[1] 1.34 µmol/L whole blood



[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]± CDC bias is the CDC assayed value minus EV.
[3]± Participant bias ($\bar{X}$ Bias) is the Participant mean assayed value minus EV, represented by the broken line. Participant mean excludes outlier values.

TABLE 7a. 2008 Quality Control Data
Summaries of Statistical Analyses

17 α-HYDROXYPROGESTERONE (ng 17-OHP/mL serum)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 751 – Enriched 25 ng/mL serum						
MP Biomedicals RIA	80	27.1	3.7	3.8	5.7	0.9
Neo-Genesis Accuwell	50	29.2	4.3	4.4	1.5	1.1
Delfia	355	27.4	3.3	4.3	3.1	1.0
AutoDelfia	1227	28.3	3.4	3.9	1.3	1.1
Bio-Rad Quantase	109	31.3	4.3	6.5	-0.8	1.3
Bayer Medical	29	31.7	2.7	3.9	7.4	1.0
LC-MS/MS	49	29.8	5.1	7.6	7.2	1.0
In House	40	26.9	3.2	6.0	5.7	0.9
Other	72	30.8	4.9	7.9	3.2	1.1
Lot 752 – Enriched 50 ng/mL serum						
MP Biomedicals RIA	79	50.8	5.5	5.5	5.7	0.9
Neo-Genesis Accuwell	48	54.3	8.6	10.5	1.5	1.1
Delfia	359	52.9	25.0	25.1	3.1	1.0
AutoDelfia	1223	55.2	6.8	8.0	1.3	1.1
Bio-Rad Quantase	109	61.8	8.1	12.4	-0.8	1.3
Bayer Medical	30	55.7	6.6	7.9	7.4	1.0
LC-MS/MS	46	58.8	11.1	18.6	7.2	1.0
In House	36	49.6	5.3	11.7	5.7	0.9
Other	68	56.5	5.7	12.9	3.2	1.1
Lot 753 – Enriched 100 ng/mL serum						
MP Biomedicals RIA	79	93.6	11.5	11.5	5.7	0.9
Neo-Genesis Accuwell	49	109.9	12.0	14.7	1.5	1.1
Delfia	344	101.5	12.2	15.6	3.1	1.0
AutoDelfia	1214	109.1	11.4	14.2	1.3	1.1
Bio-Rad Quantase	109	125.9	13.0	21.9	-0.8	1.3
Bayer Medical	28	104.4	12.9	18.6	7.4	1.0
LC-MS/MS	54	104.1	19.2	41.5	7.2	1.0
In House	43	92.0	16.3	24.1	5.7	0.9
Other	70	111.6	9.3	29.4	3.2	1.1

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7b. 2008 Quality Control Data
Summaries of Statistical Analyses

THYROXINE (μg T4/dL serum)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 701 – Enriched 2 μg/dL serum						
Siemens Healthcare Diagnostics	38	1.9	0.3	0.4	-0.2	1.0
MP Biomedicals RIA	10	1.6	0.5	0.5	0.4	0.8
Neo-Genesis Accuwell	89	0.9	0.4	0.5	-1.0	1.0
Delfia	149	1.6	0.3	0.3	0.0	0.8
AutoDelfia	712	1.6	0.4	0.4	0.0	0.8
Other	88	1.8	0.4	0.6	-0.6	1.0
Lot 702 – Enriched 7 μg/dL serum						
Siemens Healthcare Diagnostics	40	7.0	0.9	1.2	-0.2	1.0
MP Biomedicals RIA	40	6.3	0.8	1.4	0.4	0.8
Neo-Genesis Accuwell	90	6.0	1.0	1.4	-1.0	1.0
Delfia	147	6.0	0.5	0.7	0.0	0.8
AutoDelfia	709	5.8	0.6	0.7	0.0	0.8
Other	89	6.3	1.0	1.1	-0.6	1.0
Lot 703 – Enriched 11 μg/dL serum						
Siemens Healthcare Diagnostics	40	11.2	1.3	1.5	-0.2	1.0
MP Biomedicals RIA	40	9.2	0.9	2.1	0.4	0.8
Neo-Genesis Accuwell	89	9.7	1.2	1.9	-1.0	1.0
Delfia	148	9.2	0.9	1.3	0.0	0.8
AutoDelfia	717	9.0	1.0	1.2	0.0	0.8
Other	90	11.2	1.9	2.1	-0.6	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7c. 2008 Quality Control Data
Summaries of Statistical Analyses

THYROID-STIMULATING-HORMONE (μIU TSH/mL serum)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 711 – Enriched 25 μIU/mL serum						
Siemens Healthcare Diagnostics	30	26.0	3.0	3.9	0.3	1.1
Neo-Genesis Accuwell	30	28.8	4.6	5.4	-1.5	1.2
MP Biomedicals IRMA	30	32.2	2.4	7.8	5.5	1.1
MP Biomedicals ELISA	10	18.1	1.5	1.5	-1.2	0.8
Delfia	533	27.9	2.7	3.7	0.9	1.1
AutoDelfia	910	27.6	2.3	3.0	2.6	1.0
Ani Labsystems	50	29.9	2.9	3.7	2.4	1.1
Bio-Rad Quantase	30	25.6	2.5	10.5	3.4	0.8
TecnoSuma UMELISA	10	29.7	3.4	3.4	-8.9	1.5
Bioclone ELISA	49	36.9	5.2	11.0	6.9	1.2
DiaSorin	79	30.1	3.0	3.4	2.0	1.2
ECLIA	10	26.7	1.5	1.5	6.8	0.9
In House	60	28.2	3.2	3.8	1.4	1.1
Other	152	30.1	2.4	5.8	1.9	1.2
Lot 712 – Enriched 40 μIU/mL serum						
Siemens Healthcare Diagnostics	30	44.1	5.3	5.4	0.3	1.1
Neo-Genesis Accuwell	30	44.5	3.9	5.9	-1.5	1.2
MP Biomedicals IRMA	30	51.0	5.6	9.6	5.5	1.1
MP Biomedicals ELISA	10	30.2	3.4	3.4	-1.2	0.8
Delfia	561	43.8	4.7	8.0	0.9	1.1
AutoDelfia	908	44.6	3.5	4.3	2.6	1.0
Ani Labsystems	50	47.0	6.2	7.1	2.4	1.1
Bio-Rad Quantase	29	35.3	2.5	12.9	3.4	0.8
TecnoSuma UMELISA	10	51.0	9.2	9.2	-8.9	1.5
Bioclone ELISA	48	56.9	8.9	22.4	6.9	1.2
DiaSorin	76	49.0	5.7	6.6	2.0	1.2
ECLIA	10	45.0	1.4	1.4	6.8	0.9
In House	60	44.0	3.8	5.6	1.4	1.1
Other	160	50.3	4.9	9.7	1.9	1.2

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

THYROID-STIMULATING-HORMONE (μIU TSH/mL serum)

- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 713 – Enriched 80 μIU/mL serum						
Siemens Healthcare Diagnostics	28	85.0	8.1	8.3	0.3	1.1
Neo-Genesis Accuwell	30	93.1	12.2	12.5	-1.5	1.2
MP Biomedicals IRMA	30	93.6	7.7	8.6	5.5	1.1
MP Biomedicals ELISA	10	61.0	5.2	5.2	-1.2	0.8
Delfia	532	87.1	7.9	10.9	0.9	1.1
AutoDelfia	907	84.4	6.3	7.6	2.6	1.0
Ani Labsystems	46	91.0	7.1	7.8	2.4	1.1
Bio-Rad Quantase	30	71.0	11.2	35.4	3.4	0.8
TecnoSuma UMELISA	10	112.9	9.1	9.1	-8.9	1.5
Bioclone ELISA	52	104.9	14.8	38.8	6.9	1.2
DiaSorin	78	93.8	10.5	10.5	2.0	1.2
ECLIA	10	76.5	1.6	1.6	6.8	0.9
In House	60	86.9	7.9	14.0	1.4	1.1
Other	149	95.3	7.3	22.0	1.9	1.2
Lot 811 – Enriched 25 μIU/mL serum						
Siemens Healthcare Diagnostics	29	26.0	2.8	3.1	-1.4	1.0
Neo-Genesis Accuwell	40	27.0	4.0	5.8	-7.0	1.3
MP Biomedicals IRMA	29	29.1	1.9	3.8	1.4	1.0
MP Biomedicals ELISA	10	19.5	2.9	2.9	-1.7	0.8
Delfia	582	24.9	2.6	4.1	-1.4	1.0
AutoDelfia	845	25.7	2.4	2.8	-1.0	1.0
Ani Labsystems	30	24.8	2.6	2.8	-0.8	1.0
Bio-Rad Quantase	88	30.4	4.0	7.5	4.2	1.0
TecnoSuma UMELISA	10	20.1	2.8	2.8	-5.0	0.9
Bioclone ELISA	40	28.8	3.1	9.6	-1.4	1.2
DiaSorin	89	22.3	4.1	4.5	-4.4	1.0
ECLIA	10	21.3	1.0	1.0	-1.3	0.9
In House	60	28.0	2.9	4.5	1.0	1.0
Other	128	25.9	2.3	4.2	-0.8	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

THYROID-STIMULATING-HORMONE (μIU TSH/mL serum)

- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 812 – Enriched 40 μIU/mL serum						
Siemens Healthcare Diagnostics	29	37.1	3.7	3.7	-1.4	1.0
Neo-Genesis Accuwell	40	39.6	3.9	6.7	-7.0	1.3
MP Biomedicals IRMA	29	39.8	3.4	3.9	1.4	1.0
MP Biomedicals ELISA	10	27.1	4.6	4.6	-1.7	0.8
Delfia	619	37.0	6.3	8.9	-1.4	1.0
AutoDelfia	842	37.8	3.3	4.1	-1.0	1.0
Ani Labsystems	30	37.5	3.2	3.2	-0.8	1.0
Bio-Rad Quantase	87	45.4	6.3	9.3	4.2	1.0
TecnoSuma UMELISA	10	30.3	3.4	3.4	-5.0	0.9
Bioclone ELISA	40	43.6	5.3	12.0	-1.4	1.2
DiaSorin	85	33.9	4.0	4.5	-4.4	1.0
ECLIA	10	32.2	2.6	2.6	-1.3	0.9
In House	60	41.4	3.7	7.7	1.0	1.0
Other	127	39.3	4.1	8.1	-0.8	1.0
Lot 813 – Enriched 80 μIU/mL serum						
Siemens Healthcare Diagnostics	30	81.3	5.8	6.7	-1.4	1.0
Neo-Genesis Accuwell	40	94.5	10.3	13.2	-7.0	1.3
MP Biomedicals IRMA	30	84.3	6.8	7.3	1.4	1.0
MP Biomedicals ELISA	10	61.2	9.3	9.3	-1.7	0.8
Delfia	564	79.3	6.4	11.8	-1.4	1.0
AutoDelfia	839	80.7	6.6	8.4	-1.0	1.0
Ani Labsystems	30	78.5	6.0	8.1	-0.8	1.0
Bio-Rad Quantase	88	87.2	11.6	17.1	4.2	1.0
TecnoSuma UMELISA	10	70.7	4.4	4.4	-5.0	0.9
Bioclone ELISA	40	92.1	12.1	27.8	-1.4	1.2
DiaSorin	86	77.1	8.0	10.1	-4.4	1.0
ECLIA	10	68.5	1.9	1.9	-1.3	0.9
In House	60	84.6	8.1	18.6	1.0	1.0
Other	128	82.2	7.4	17.2	-0.8	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7d. 2008 Quality Control Data
Summaries of Statistical Analyses

IMMUNOREACTIVE TRYPSINOGEN (ng IRT/mL whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 791 – Assayed 16.1 ng/mL blood						
MP Biomedicals ELISA	20	29.4	3.1	10.6	1.7	1.4
Delfia	419	16.1	2.4	2.9	-0.3	1.1
AutoDelfia	1043	16.9	1.7	2.0	-1.7	1.2
Bio-Rad Quantase	90	13.2	2.7	4.5	-2.4	0.9
Bioclone ELISA	29	13.1	1.6	1.9	-7.1	0.9
Other	29	16.5	2.0	2.1	1.6	0.9
Lot 792 – Assayed 38.8 ng/mL blood						
MP Biomedicals ELISA	20	55.5	9.5	18.5	1.7	1.4
Delfia	409	40.3	4.6	5.8	-0.3	1.1
AutoDelfia	1043	43.4	4.2	5.0	-1.7	1.2
Bio-Rad Quantase	90	31.2	4.4	16.4	-2.4	0.9
Bioclone ELISA	30	28.1	2.5	6.3	-7.1	0.9
Other	30	38.6	5.6	9.0	1.6	0.9
Lot 793 – Assayed 69.2 ng/mL blood						
MP Biomedicals ELISA	20	86.5	10.6	11.7	1.7	1.4
Delfia	410	74.8	7.9	10.6	-0.3	1.1
AutoDelfia	1058	81.7	8.4	10.3	-1.7	1.2
Bio-Rad Quantase	88	55.0	7.4	26.6	-2.4	0.9
Bioclone ELISA	30	52.2	12.3	16.7	-7.1	0.9
Other	30	67.5	6.5	8.9	1.6	0.9
Lot 794 – Assayed 133.7 ng/mL blood						
MP Biomedicals ELISA	20	190.7	17.6	41.7	1.7	1.4
Delfia	408	140.3	13.4	17.3	-0.3	1.1
AutoDelfia	1068	155.3	14.1	18.2	-1.7	1.2
Bio-Rad Quantase	86	115.4	21.3	51.7	-2.4	0.9
Bioclone ELISA	29	122.8	27.2	48.3	-7.1	0.9
Other	30	128.1	12.3	24.7	1.6	0.9

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7e. 2008 Quality Control Data
Summaries of Statistical Analyses

TOTAL GALACTOSE (mg Gal/dL whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 725 – Enriched 5 mg/dL whole blood						
Fluorometric Manual	106	5.1	1.0	1.4	0.1	1.0
Fluorometric Cont Flow, Kit	10	5.2	1.2	1.2	1.7	0.8
Colorimetric	20	5.4	1.0	1.2	-1.0	1.2
PerkinElmer Neonatal Kit	77	5.4	0.6	0.9	1.2	0.9
Neo-Genesis Accuwell	50	5.5	0.7	1.4	0.9	1.0
Bio-Rad Quantase	169	6.4	1.0	1.7	-0.7	1.5
MP Biomedicals Enzyme Assay	40	9.2	1.1	2.1	3.4	1.3
Interscientific Enzyme	34	5.5	0.7	0.9	-0.3	1.1
Astoria-Pacific	120	7.4	0.9	1.5	2.1	1.1
R&D Diagnostics Greece	30	5.8	0.8	1.3	0.9	1.0
Other	97	5.9	1.5	2.3	0.5	1.1
Lot 726 – Enriched 10 mg/dL whole blood						
Fluorometric Manual	107	10.0	1.1	1.5	0.1	1.0
Fluorometric Cont Flow, Kit	10	10.0	0.9	0.9	1.7	0.8
Colorimetric	20	10.8	1.4	1.5	-1.0	1.2
PerkinElmer Neonatal Kit	77	9.8	0.8	1.2	1.2	0.9
Neo-Genesis Accuwell	49	11.5	1.1	1.1	0.9	1.0
Bio-Rad Quantase	180	14.2	1.7	3.1	-0.7	1.5
MP Biomedicals Enzyme Assay	39	16.4	1.3	3.8	3.4	1.3
Interscientific Enzyme	42	10.6	2.4	2.4	-0.3	1.1
Astoria-Pacific	120	12.3	1.1	1.8	2.1	1.1
R&D Diagnostics Greece	30	11.0	0.8	1.1	0.9	1.0
Other	100	11.7	2.0	3.6	0.5	1.1

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TOTAL GALACTOSE (mg Gal/dL whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 727 – Enriched 15 mg/dL whole blood						
Fluorometric Manual	107	15.7	1.3	1.6	0.1	1.0
Fluorometric Cont Flow, Kit	10	14.4	0.8	0.8	1.7	0.8
Colorimetric	19	17.3	2.4	2.6	-1.0	1.2
PerkinElmer Neonatal Kit	78	14.7	0.8	1.4	1.2	0.9
Neo-Genesis Accuwell	50	16.6	1.2	1.3	0.9	1.0
Bio-Rad Quantase	180	21.3	2.6	5.3	-0.7	1.5
MP Biomedicals Enzyme Assay	39	25.7	1.3	1.8	3.4	1.3
Interscientific Enzyme	38	16.3	2.3	2.5	-0.3	1.1
Astoria-Pacific	120	18.2	1.7	2.3	2.1	1.1
R&D Diagnostics Greece	30	15.3	1.1	1.4	0.9	1.0
Other	98	17.8	2.6	5.5	0.5	1.1
Lot 728 – Enriched 30 mg/dL whole blood						
Fluorometric Manual	106	30.4	2.4	2.7	0.1	1.0
Fluorometric Cont Flow, Kit	10	25.7	1.6	1.6	1.7	0.8
Colorimetric	20	35.5	5.0	7.4	-1.0	1.2
PerkinElmer Neonatal Kit	78	27.1	1.6	2.2	1.2	0.9
Neo-Genesis Accuwell	50	31.4	2.1	2.4	0.9	1.0
Bio-Rad Quantase	170	43.3	5.1	9.2	-0.7	1.5
MP Biomedicals Enzyme Assay	40	43.0	1.8	3.0	3.4	1.3
Interscientific Enzyme	38	33.3	3.0	8.6	-0.3	1.1
Astoria-Pacific	120	33.6	3.6	4.1	2.1	1.1
R&D Diagnostics Greece	30	30.5	2.0	4.7	0.9	1.0
Other	98	34.0	4.9	10.1	0.5	1.1

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TOTAL GALACTOSE (mg Gal/dL whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 821 – Enriched 5 mg/dL whole blood						
Fluorometric Manual	117	5.2	1.1	1.7	0.1	1.0
Colorimetric	30	6.5	1.6	1.6	0.0	1.3
PerkinElmer Neonatal Kit	96	4.2	0.6	1.9	0.8	0.8
Neo-Genesis Accuwell	40	6.1	0.5	0.6	1.2	1.0
Bio-Rad Quantase	128	8.3	0.9	1.4	-1.2	1.8
MP Biomedicals Enzyme Assay	30	10.4	0.8	1.0	4.1	1.4
Interscientific Enzyme	30	5.7	0.7	0.8	1.3	0.9
Astoria-Pacific	139	7.7	1.0	2.4	1.9	1.1
TecnoSuma UMTEST	10	5.7	0.4	0.4	1.2	1.0
R&D Diagnostics Greece	30	6.2	0.4	1.2	2.6	0.7
Other	98	6.5	1.5	1.9	-0.3	1.3
Lot 822 – Enriched 10 mg/dL whole blood						
Fluorometric Manual	118	10.2	1.1	2.4	0.1	1.0
Colorimetric	30	12.9	1.9	1.9	0.0	1.3
PerkinElmer Neonatal Kit	99	9.5	0.8	3.0	0.8	0.8
Neo-Genesis Accuwell	40	10.7	0.6	0.8	1.2	1.0
Bio-Rad Quantase	128	16.2	2.3	3.4	-1.2	1.8
MP Biomedicals Enzyme Assay	29	18.1	1.2	1.9	4.1	1.4
Interscientific Enzyme	30	9.8	1.1	1.6	1.3	0.9
Astoria-Pacific	139	12.2	1.1	3.6	1.9	1.1
TecnoSuma UMTEST	10	11.4	0.3	0.3	1.2	1.0
R&D Diagnostics Greece	30	9.8	0.9	3.2	2.6	0.7
Other	98	12.4	2.0	2.5	-0.3	1.3

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TOTAL GALACTOSE (mg Gal/dL whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 823 – Enriched 15 mg/dL whole blood						
Fluorometric Manual	114	15.5	1.2	2.8	0.1	1.0
Colorimetric	30	19.0	2.6	2.6	0.0	1.3
PerkinElmer Neonatal Kit	97	12.8	1.3	3.8	0.8	0.8
Neo-Genesis Accuwell	40	15.5	1.0	1.1	1.2	1.0
Bio-Rad Quantase	125	25.9	2.4	4.6	-1.2	1.8
MP Biomedicals Enzyme Assay	29	26.9	1.1	1.4	4.1	1.4
Interscientific Enzyme	30	14.8	1.2	1.6	1.3	0.9
Astoria-Pacific	130	19.0	1.7	2.5	1.9	1.1
TecnoSuma UMTEST	10	16.2	0.7	0.7	1.2	1.0
R&D Diagnostics Greece	30	14.5	1.1	4.1	2.6	0.7
Other	96	19.1	2.1	3.4	-0.3	1.3
Lot 824 – Enriched 30 mg/dL whole blood						
Fluorometric Manual	120	30.5	2.2	4.2	0.1	1.0
Colorimetric	30	38.5	3.7	5.5	0.0	1.3
PerkinElmer Neonatal Kit	99	24.5	2.2	5.1	0.8	0.8
Neo-Genesis Accuwell	40	30.0	2.2	2.2	1.2	1.0
Bio-Rad Quantase	110	53.2	6.6	12.0	-1.2	1.8
MP Biomedicals Enzyme Assay	30	45.8	1.5	4.5	4.1	1.4
Interscientific Enzyme	30	27.5	2.5	3.0	1.3	0.9
Astoria-Pacific	130	34.8	3.0	4.1	1.9	1.1
TecnoSuma UMTEST	10	30.7	1.3	1.3	1.2	1.0
R&D Diagnostics Greece	30	24.9	1.5	6.8	2.6	0.7
Other	97	38.8	6.5	9.2	-0.3	1.3

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7f. 2008 Quality Control Data
Summaries of Statistical Analyses

PHENYLALANINE (mg Phe/dL whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 725 – Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	20	1.6	0.3	0.6	1.7	0.8
Fluorometric Manual	60	2.2	0.2	0.6	2.2	0.9
Fluorometric Cont Flow, In house	10	2.3	0.2	0.2	2.4	0.9
Fluorometric Cont Flow, Kit	76	2.0	0.2	0.5	2.1	1.0
Colorimetric	90	2.3	0.2	0.3	2.2	1.1
PerkinElmer Neonatal Kit	305	1.7	0.3	0.4	1.7	0.9
Neo-Genesis Accuwell	30	1.9	0.2	0.2	1.9	1.0
Ani Labsystems	59	2.0	0.3	0.3	1.9	1.0
Bio-Rad Quantase	79	1.5	0.3	0.4	1.4	1.0
MP Biomedicals Enzyme Assay	10	2.3	0.2	0.2	1.7	0.9
Interscientific Enzyme	30	1.5	0.3	0.4	1.5	0.8
Astoria-Pacific	20	2.9	0.1	0.1	2.8	1.2
HPLC	49	1.7	0.2	0.2	1.7	0.9
Derivatized - MS/MS Non-kit	696	1.6	0.1	0.2	1.6	0.9
Non-derivatized - MS/MS Non-kit	138	1.8	0.2	0.3	1.7	0.9
Derivatized - MS/MS PE NeoGram MS2 Kit	288	1.7	0.2	0.2	1.7	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	1.8	0.1	0.1	1.8	0.9
TecnoSuma UMTEST	30	2.0	0.4	0.7	1.6	1.0
Other	40	2.1	0.5	0.8	2.1	1.0
Lot 726 – Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	29	4.1	0.2	0.3	1.7	0.8
Fluorometric Manual	59	4.6	0.4	0.7	2.2	0.9
Fluorometric Cont Flow, In house	10	5.0	0.2	0.2	2.4	0.9
Fluorometric Cont Flow, Kit	77	5.0	0.3	0.9	2.1	1.0
Colorimetric	89	5.5	0.3	1.3	2.2	1.1
PerkinElmer Neonatal Kit	298	4.2	0.5	0.7	1.7	0.9
Neo-Genesis Accuwell	29	4.9	0.4	0.4	1.9	1.0
Ani Labsystems	58	4.7	0.4	0.6	1.9	1.0
Bio-Rad Quantase	79	4.3	0.5	0.6	1.4	1.0
MP Biomedicals Enzyme Assay	20	4.1	0.6	0.7	1.7	0.9
Interscientific Enzyme	30	3.9	0.4	0.6	1.5	0.8
Astoria-Pacific	20	6.3	0.5	0.5	2.8	1.2
HPLC	49	4.2	0.2	0.4	1.7	0.9
Derivatized - MS/MS Non-kit	695	4.2	0.3	0.6	1.6	0.9
Non-derivatized - MS/MS Non-kit	138	4.5	0.3	0.8	1.7	0.9
Derivatized - MS/MS PE NeoGram MS2 Kit	288	4.4	0.5	0.6	1.7	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	4.6	0.4	0.8	1.8	0.9
TecnoSuma UMTEST	29	4.4	0.8	1.1	1.6	1.0
Other	40	5.0	0.5	1.5	2.1	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PHENYLALANINE (mg Phe/dL whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 727 – Enriched 7 mg/dL whole blood						
Bacterial Inhibition Assays	30	7.6	0.7	0.8	1.7	0.8
Fluorometric Manual	50	8.5	0.6	0.6	2.2	0.9
Fluorometric Cont Flow, In house	10	9.4	1.0	1.0	2.4	0.9
Fluorometric Cont Flow, Kit	76	9.0	0.5	1.4	2.1	1.0
Colorimetric	90	10.3	0.7	2.0	2.2	1.1
PerkinElmer Neonatal Kit	306	7.9	1.1	1.6	1.7	0.9
Neo-Genesis Accuwell	30	9.1	0.6	0.8	1.9	1.0
Ani Labsystems	59	8.9	0.6	1.2	1.9	1.0
Bio-Rad Quantase	78	8.7	0.8	1.0	1.4	1.0
MP Biomedicals Enzyme Assay	19	7.9	0.9	1.0	1.7	0.9
Interscientific Enzyme	30	7.3	0.6	0.9	1.5	0.8
Astoria-Pacific	19	10.9	0.5	0.6	2.8	1.2
HPLC	50	8.2	0.5	0.7	1.7	0.9
Derivatized - MS/MS Non-kit	705	7.9	0.6	1.1	1.6	0.9
Non-derivatized - MS/MS Non-kit	138	8.5	0.9	1.5	1.7	0.9
Derivatized - MS/MS PE NeoGram MS2 Kit	289	8.2	0.7	1.0	1.7	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	8.6	0.8	1.2	1.8	0.9
TecnoSuma UMTEST	30	7.9	0.9	1.4	1.6	1.0
Other	40	9.2	0.6	2.7	2.1	1.0
Lot 728 – Enriched 11 mg/dL whole blood						
Bacterial Inhibition Assays	30	10.6	1.0	1.1	1.7	0.8
Fluorometric Manual	60	11.5	1.0	1.9	2.2	0.9
Fluorometric Cont Flow, In house	10	11.9	0.8	0.8	2.4	0.9
Fluorometric Cont Flow, Kit	77	12.8	0.8	2.1	2.1	1.0
Colorimetric	89	14.6	1.1	3.9	2.2	1.1
PerkinElmer Neonatal Kit	302	11.3	1.0	1.7	1.7	0.9
Neo-Genesis Accuwell	30	13.1	0.8	0.9	1.9	1.0
Ani Labsystems	60	12.6	0.8	1.6	1.9	1.0
Bio-Rad Quantase	80	12.6	1.4	1.8	1.4	1.0
MP Biomedicals Enzyme Assay	20	11.9	0.9	0.9	1.7	0.9
Interscientific Enzyme	30	10.5	0.7	1.6	1.5	0.8
Astoria-Pacific	19	15.6	0.7	0.7	2.8	1.2
HPLC	50	11.2	0.6	1.1	1.7	0.9
Derivatized - MS/MS Non-kit	707	11.5	0.9	1.7	1.6	0.9
Non-derivatized - MS/MS Non-kit	140	12.1	1.2	2.0	1.7	0.9
Derivatized - MS/MS PE NeoGram MS2 Kit	288	11.7	1.1	1.5	1.7	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	12.0	1.4	1.9	1.8	0.9
TecnoSuma UMTEST	30	13.3	1.6	2.0	1.6	1.0
Other	40	13.3	0.7	4.4	2.1	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PHENYLALANINE (mg Phe/dL whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 821 – Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	10	1.2	0.2	0.2	1.2	0.9
Fluorometric Manual	59	1.6	0.2	0.3	1.8	1.0
Fluorometric Cont Flow, In house	12	2.3	0.1	0.4	2.6	0.9
Fluorometric Cont Flow, Kit	68	1.7	0.2	0.5	1.7	1.1
Colorimetric	80	1.8	0.3	0.3	1.8	1.3
PerkinElmer Neonatal Kit	247	1.4	0.2	0.3	1.4	1.0
Neo-Genesis Accuwell	20	1.5	0.3	0.4	1.5	1.1
Ani Labsystems	60	1.7	0.2	0.3	1.7	1.1
Bio-Rad Quantase	97	1.6	0.3	0.4	1.5	1.1
MP Biomedicals Enzyme Assay	29	1.6	0.3	0.3	1.6	1.2
Interscientific Enzyme	30	1.3	0.3	0.3	1.3	0.8
Astoria-Pacific	20	2.5	0.2	0.3	2.5	1.4
HPLC	59	1.3	0.1	0.2	1.4	0.9
Derivatized - MS/MS Non-kit	727	1.3	0.1	0.2	1.3	0.9
Non-derivatized - MS/MS Non-kit	159	1.4	0.1	0.3	1.4	1.0
Derivatized - MS/MS PE NeoGram MS2 Kit	296	1.4	0.1	0.2	1.4	1.0
Non-derivatized - MS/MS PE NeoGram MS2 Kit	60	1.5	0.1	0.2	1.5	1.1
Derivatized - MS/MS Chromsystems Kit	10	1.4	0.2	0.2	1.3	1.0
TecnoSuma UMTEST	28	1.9	0.3	0.5	1.5	1.1
Other	40	1.8	0.3	0.6	1.6	1.2
Lot 822 – Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	10	4.0	0.2	0.2	1.2	0.9
Fluorometric Manual	60	4.9	0.4	0.6	1.8	1.0
Fluorometric Cont Flow, In house	12	5.6	0.5	1.3	2.6	0.9
Fluorometric Cont Flow, Kit	70	5.0	0.4	1.0	1.7	1.1
Colorimetric	80	5.7	0.3	0.7	1.8	1.3
PerkinElmer Neonatal Kit	247	4.2	0.4	0.6	1.4	1.0
Neo-Genesis Accuwell	19	4.6	0.3	0.3	1.5	1.1
Ani Labsystems	60	5.0	0.5	1.0	1.7	1.1
Bio-Rad Quantase	99	4.7	0.6	1.0	1.5	1.1
MP Biomedicals Enzyme Assay	30	4.9	0.7	0.8	1.6	1.2
Interscientific Enzyme	30	3.7	0.3	0.4	1.3	0.8
Astoria-Pacific	20	6.4	0.5	0.5	2.5	1.4
HPLC	59	4.2	0.3	0.4	1.4	0.9
Derivatized - MS/MS Non-kit	725	4.1	0.3	0.6	1.3	0.9
Non-derivatized - MS/MS Non-kit	159	4.5	0.4	0.7	1.4	1.0
Derivatized - MS/MS PE NeoGram MS2 Kit	296	4.4	0.4	0.6	1.4	1.0
Non-derivatized - MS/MS PE NeoGram MS2 Kit	60	4.7	0.3	0.6	1.5	1.1
Derivatized - MS/MS Chromsystems Kit	10	4.3	0.4	0.4	1.3	1.0
TecnoSuma UMTEST	27	4.2	0.4	0.7	1.5	1.1
Other	40	5.1	0.4	1.1	1.6	1.2

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PHENYLALANINE (mg Phe/dL whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 823 – Enriched 7 mg/dL whole blood						
Bacterial Inhibition Assays	10	7.8	0.3	0.3	1.2	0.9
Fluorometric Manual	50	8.9	0.8	0.8	1.8	1.0
Fluorometric Cont Flow, In house	12	9.4	0.6	1.1	2.6	0.9
Fluorometric Cont Flow, Kit	70	9.3	0.8	1.8	1.7	1.1
Colorimetric	80	11.6	0.6	1.5	1.8	1.3
PerkinElmer Neonatal Kit	244	8.0	0.7	1.1	1.4	1.0
Neo-Genesis Accuwell	20	9.1	0.5	0.6	1.5	1.1
Ani Labsystems	59	9.6	0.8	1.4	1.7	1.1
Bio-Rad Quantase	99	9.5	0.9	1.7	1.5	1.1
MP Biomedicals Enzyme Assay	29	10.0	0.9	1.2	1.6	1.2
Interscientific Enzyme	30	7.1	0.6	1.0	1.3	0.8
Astoria-Pacific	20	12.5	1.0	1.0	2.5	1.4
HPLC	60	8.1	0.5	0.6	1.4	0.9
Derivatized - MS/MS Non-kit	729	7.8	0.7	1.3	1.3	0.9
Non-derivatized - MS/MS Non-kit	159	8.9	0.8	1.6	1.4	1.0
Derivatized - MS/MS PE NeoGram MS2 Kit	295	8.4	0.7	1.1	1.4	1.0
Non-derivatized - MS/MS PE NeoGram MS2 Kit	60	9.6	0.6	1.3	1.5	1.1
Derivatized - MS/MS Chromsystems Kit	10	8.5	0.4	0.4	1.3	1.0
TecnoSuma UMTEST	28	8.5	1.1	1.9	1.5	1.1
Other	40	9.8	0.7	2.0	1.6	1.2
Lot 824 – Enriched 11 mg/dL whole blood						
Bacterial Inhibition Assays	10	11.5	0.5	0.5	1.2	0.9
Fluorometric Manual	60	12.6	0.7	0.7	1.8	1.0
Fluorometric Cont Flow, In house	12	12.6	0.7	0.8	2.6	0.9
Fluorometric Cont Flow, Kit	70	13.6	0.9	2.6	1.7	1.1
Colorimetric	79	16.5	0.7	2.1	1.8	1.3
PerkinElmer Neonatal Kit	235	11.9	0.9	1.5	1.4	1.0
Neo-Genesis Accuwell	20	13.5	1.0	1.0	1.5	1.1
Ani Labsystems	60	13.6	1.1	2.0	1.7	1.1
Bio-Rad Quantase	88	14.1	1.2	2.3	1.5	1.1
MP Biomedicals Enzyme Assay	30	14.5	1.3	1.5	1.6	1.2
Interscientific Enzyme	30	10.6	0.8	1.7	1.3	0.8
Astoria-Pacific	20	17.3	0.5	0.7	2.5	1.4
HPLC	60	11.6	0.7	1.0	1.4	0.9
Derivatized - MS/MS Non-kit	721	11.3	0.9	1.7	1.3	0.9
Non-derivatized - MS/MS Non-kit	160	12.9	1.0	2.1	1.4	1.0
Derivatized - MS/MS PE NeoGram MS2 Kit	298	12.2	1.1	1.8	1.4	1.0
Non-derivatized - MS/MS PE NeoGram MS2 Kit	59	13.5	0.8	1.6	1.5	1.1
Derivatized - MS/MS Chromsystems Kit	10	11.7	0.8	0.8	1.5	0.9
TecnoSuma UMTEST	27	13.4	1.3	1.5	1.5	1.1
Other	40	15.1	1.5	3.9	1.6	1.2

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7g. 2008 Quality Control Data
Summaries of Statistical Analyses

LEUCINE (mg Leu/dL whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 725 – Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	20	2.6	0.4	0.5	2.2	1.1
Colorimetric	10	5.0	0.7	0.7	5.1	1.2
Bio-Rad Quantase	10	3.7	0.2	0.2	3.6	1.2
Interscientific Enzyme	20	3.3	0.3	0.4	3.4	0.7
HPLC	19	2.3	0.2	0.2	2.3	0.9
Derivatized - MS/MS Non-kit	678	2.9	0.3	0.5	2.7	0.9
Non-derivatized - MS/MS Non-kit	69	3.3	0.3	0.5	3.2	0.8
Derivatized - MS/MS PE NeoGram MS2 Kit	294	2.6	0.3	0.4	2.5	0.8
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	3.1	0.5	0.5	3.0	0.7
Lot 726 – Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	20	5.4	0.8	1.1	2.2	1.1
Colorimetric	9	8.4	0.8	0.8	5.1	1.2
Bio-Rad Quantase	10	6.9	0.4	0.4	3.6	1.2
Interscientific Enzyme	20	5.8	0.3	0.3	3.4	0.7
HPLC	20	4.9	0.2	0.6	2.3	0.9
Derivatized - MS/MS Non-kit	689	5.1	0.5	1.0	2.7	0.9
Non-derivatized - MS/MS Non-kit	69	5.4	0.4	0.8	3.2	0.8
Derivatized - MS/MS PE NeoGram MS2 Kit	295	4.8	0.4	0.6	2.5	0.8
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	5.1	0.7	0.9	3.0	0.7
Lot 727 – Enriched 7 mg/dL whole blood						
Bacterial Inhibition Assays	19	8.8	0.3	0.4	2.2	1.1
Colorimetric	10	14.2	1.1	1.1	5.1	1.2
Bio-Rad Quantase	10	12.9	0.6	0.6	3.6	1.2
Interscientific Enzyme	19	8.7	0.5	0.6	3.4	0.7
HPLC	20	8.9	0.4	0.9	2.3	0.9
Derivatized - MS/MS Non-kit	688	8.9	2.0	2.5	2.7	0.9
Non-derivatized - MS/MS Non-kit	69	8.9	0.7	1.1	3.2	0.8
Derivatized - MS/MS PE NeoGram MS2 Kit	303	8.2	0.8	1.2	2.5	0.8
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	8.1	0.8	1.0	3.0	0.7
Lot 727 – Enriched 11 mg/dL whole blood						
Bacterial Inhibition Assays	20	14.4	1.8	4.0	2.2	1.1
Colorimetric	10	17.9	1.7	1.7	5.1	1.2
Bio-Rad Quantase	10	16.8	0.9	0.9	3.6	1.2
Interscientific Enzyme	20	11.4	0.6	0.6	3.4	0.7
HPLC	20	12.1	0.4	1.7	2.3	0.9
Derivatized - MS/MS Non-kit	676	12.4	1.1	2.1	2.7	0.9
Non-derivatized - MS/MS Non-kit	69	11.7	1.0	1.3	3.2	0.8
Derivatized - MS/MS PE NeoGram MS2 Kit	294	11.5	1.0	1.5	2.5	0.8
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	11.1	1.3	1.5	3.0	0.7

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

LEUCINE (mg Leu/dL whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 821 – Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	20	1.9	0.4	0.6	1.7	1.2
Bio-Rad Quantase	10	2.7	0.2	0.2	2.8	1.0
Interscientific Enzyme	10	3.1	0.2	0.2	3.3	0.9
HPLC	30	1.5	0.2	0.2	1.7	1.1
Derivatized - MS/MS Non-kit	697	2.2	0.2	0.5	2.3	1.1
Non-derivatized - MS/MS Non-kit	89	2.4	0.2	0.3	2.5	1.1
Derivatized - MS/MS PE NeoGram MS2 Kit	295	2.0	0.2	0.3	2.1	1.1
Non-derivatized - MS/MS PE NeoGram MS2 Kit	59	2.2	0.2	0.4	2.2	1.0
Derivatized - MS/MS Chromsystems Kit	10	2.1	0.2	0.2	2.3	1.1
Lot 822 – Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	20	5.4	0.8	1.3	1.7	1.2
Bio-Rad Quantase	10	6.0	0.3	0.3	2.8	1.0
Interscientific Enzyme	10	6.1	0.5	0.5	3.3	0.9
HPLC	30	5.3	0.3	0.5	1.7	1.1
Derivatized - MS/MS Non-kit	700	5.7	0.5	1.0	2.3	1.1
Non-derivatized - MS/MS Non-kit	89	5.7	0.3	0.6	2.5	1.1
Derivatized - MS/MS PE NeoGram MS2 Kit	293	5.5	0.5	0.7	2.1	1.1
Non-derivatized - MS/MS PE NeoGram MS2 Kit	60	5.4	0.5	1.0	2.2	1.0
Derivatized - MS/MS Chromsystems Kit	10	5.5	0.4	0.4	2.3	1.1
Lot 823 – Enriched 7 mg/dL whole blood						
Bacterial Inhibition Assays	20	9.7	1.3	1.8	1.7	1.2
Bio-Rad Quantase	10	10.1	0.5	0.5	2.8	1.0
Interscientific Enzyme	10	10.1	1.1	1.1	3.3	0.9
HPLC	30	10.2	0.4	1.1	1.7	1.1
Derivatized - MS/MS Non-kit	700	10.0	0.8	1.8	2.3	1.1
Non-derivatized - MS/MS Non-kit	89	10.0	0.7	1.3	2.5	1.1
Derivatized - MS/MS PE NeoGram MS2 Kit	295	9.8	0.8	1.4	2.1	1.1
Non-derivatized - MS/MS PE NeoGram MS2 Kit	59	9.5	0.5	1.2	2.2	1.0
Derivatized - MS/MS Chromsystems Kit	10	10.2	0.4	0.4	2.3	1.1
Lot 824 – Enriched 11 mg/dL whole blood						
Bacterial Inhibition Assays	20	15.7	1.7	3.6	1.7	1.2
Bio-Rad Quantase	10	14.2	0.5	0.5	2.8	1.0
Interscientific Enzyme	10	13.0	1.1	1.1	3.3	0.9
HPLC	30	14.1	1.1	1.8	1.7	1.1
Derivatized - MS/MS Non-kit	698	14.2	1.0	2.5	2.3	1.1
Non-derivatized - MS/MS Non-kit	80	14.1	1.2	2.2	2.5	1.1
Derivatized - MS/MS PE NeoGram MS2 Kit	297	14.0	1.3	2.1	2.1	1.1
Non-derivatized - MS/MS PE NeoGram MS2 Kit	59	13.7	0.7	2.0	2.2	1.0
Derivatized - MS/MS Chromsystems Kit	10	13.6	0.8	0.8	2.3	1.1

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7h. 2008 Quality Control Data
Summaries of Statistical Analyses

METHIONINE (mg Met/dL whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 725 – Nonenriched 0 mg/dL whole blood						
HPLC	20	0.4	0.1	0.1	0.5	0.8
Derivatized - MS/MS Non-kit	649	0.5	0.1	0.1	0.5	0.8
Non-derivatized - MS/MS Non-kit	67	0.5	0.1	0.2	0.5	0.9
Derivatized - MS/MS PE NeoGram MS2 Kit	279	0.5	0.1	0.1	0.6	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	0.4	0.1	0.1	0.4	0.8
Lot 726 – Enriched 1 mg/dL whole blood						
HPLC	20	1.3	0.1	0.1	0.5	0.8
Derivatized - MS/MS Non-kit	647	1.3	0.1	0.2	0.5	0.8
Non-derivatized - MS/MS Non-kit	68	1.4	0.2	0.3	0.5	0.9
Derivatized - MS/MS PE NeoGram MS2 Kit	277	1.4	0.2	0.2	0.6	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	1.2	0.2	0.3	0.4	0.8
Lot 727 – Enriched 3 mg/dL whole blood						
HPLC	20	3.3	0.2	0.3	0.5	0.8
Derivatized - MS/MS Non-kit	641	3.1	0.3	0.5	0.5	0.8
Non-derivatized - MS/MS Non-kit	66	3.3	0.4	0.5	0.5	0.9
Derivatized - MS/MS PE NeoGram MS2 Kit	274	3.3	0.3	0.4	0.6	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	38	2.9	0.3	0.3	0.4	0.8
Lot 728 – Enriched 6 mg/dL whole blood						
HPLC	20	5.5	0.3	0.6	0.5	0.8
Derivatized - MS/MS Non-kit	638	5.4	0.5	1.0	0.5	0.8
Non-derivatized - MS/MS Non-kit	66	5.7	0.5	0.8	0.5	0.9
Derivatized - MS/MS PE NeoGram MS2 Kit	276	5.6	0.5	0.7	0.6	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	38	5.0	0.4	0.5	0.4	0.8

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

METHIONINE (mg Met/dL whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 821 – Nonenriched 0 mg/dL whole blood						
HPLC	18	0.3	0.0	0.0	0.4	0.8
Derivatized - MS/MS Non-kit	670	0.4	0.1	0.1	0.4	0.8
Non-derivatized - MS/MS Non-kit	92	0.4	0.1	0.3	0.4	1.0
Derivatized - MS/MS PE NeoGram MS2 Kit	276	0.4	0.1	0.1	0.4	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	60	0.3	0.1	0.1	0.4	0.8
Derivatized - MS/MS Chromsystems Kit	10	0.4	0.1	0.1	0.4	0.8
Lot 822 – Enriched 1 mg/dL whole blood						
HPLC	20	1.2	0.1	0.1	0.4	0.8
Derivatized - MS/MS Non-kit	681	1.4	0.1	0.2	0.4	0.8
Non-derivatized - MS/MS Non-kit	90	1.3	0.1	0.3	0.4	1.0
Derivatized - MS/MS PE NeoGram MS2 Kit	275	1.5	0.2	0.2	0.4	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	56	1.1	0.1	0.2	0.4	0.8
Derivatized - MS/MS Chromsystems Kit	10	1.2	0.2	0.2	0.4	0.8
Lot 823 – Enriched 3 mg/dL whole blood						
HPLC	20	3.0	0.2	0.2	0.4	0.8
Derivatized - MS/MS Non-kit	661	3.0	0.3	0.5	0.4	0.8
Non-derivatized - MS/MS Non-kit	94	3.3	0.4	1.7	0.4	1.0
Derivatized - MS/MS PE NeoGram MS2 Kit	278	3.2	0.3	0.5	0.4	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	59	2.8	0.3	0.4	0.4	0.8
Derivatized - MS/MS Chromsystems Kit	10	3.1	0.3	0.3	0.4	0.8
Lot 824 – Enriched 6 mg/dL whole blood						
HPLC	19	5.1	0.3	0.3	0.4	0.8
Derivatized - MS/MS Non-kit	675	5.5	0.5	0.9	0.4	0.8
Non-derivatized - MS/MS Non-kit	86	6.2	0.5	2.6	0.4	1.0
Derivatized - MS/MS PE NeoGram MS2 Kit	278	6.0	0.6	0.9	0.4	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	59	4.9	0.6	1.0	0.4	0.8
Derivatized - MS/MS Chromsystems Kit	10	5.4	0.7	0.7	0.4	0.8

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7i. 2008 Quality Control Data
Summaries of Statistical Analyses

TYROSINE (mg Tyr/dL whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 725 – Nonenriched 0 mg/dL whole blood						
Fluorometric Manual	10	2.5	0.3	0.3	2.3	1.0
HPLC	40	1.3	0.1	0.3	1.3	0.8
Derivatized - MS/MS Non-kit	702	1.3	0.1	0.3	1.3	0.8
Non-derivatized - MS/MS Non-kit	128	1.4	0.2	0.3	1.3	0.9
Derivatized - MS/MS PE NeoGram MS2 Kit	284	1.3	0.1	0.2	1.3	0.8
Non-derivatized - MS/MS PE NeoGram MS2 Kit	48	1.3	0.2	0.2	1.2	0.8
Lot 726 – Enriched 3 mg/dL whole blood						
Fluorometric Manual	10	5.1	0.4	0.4	2.3	1.0
HPLC	40	3.6	0.2	0.5	1.3	0.8
Derivatized - MS/MS Non-kit	712	3.7	0.4	0.7	1.3	0.8
Non-derivatized - MS/MS Non-kit	128	3.9	0.4	0.8	1.3	0.9
Derivatized - MS/MS PE NeoGram MS2 Kit	286	3.7	0.3	0.4	1.3	0.8
Non-derivatized - MS/MS PE NeoGram MS2 Kit	46	3.5	0.4	0.5	1.2	0.8
Lot 727 – Enriched 7 mg/dL whole blood						
Fluorometric Manual	10	9.3	0.8	0.8	2.3	1.0
HPLC	40	7.1	0.3	1.0	1.3	0.8
Derivatized - MS/MS Non-kit	709	7.2	0.7	1.3	1.3	0.8
Non-derivatized - MS/MS Non-kit	130	7.5	1.0	1.7	1.3	0.9
Derivatized - MS/MS PE NeoGram MS2 Kit	286	7.2	0.6	0.8	1.3	0.8
Non-derivatized - MS/MS PE NeoGram MS2 Kit	47	6.9	0.6	0.8	1.2	0.8
Lot 728 – Enriched 11 mg/dL whole blood						
Fluorometric Manual	10	13.7	1.4	1.4	2.3	1.0
HPLC	40	10.0	0.5	0.9	1.3	0.8
Derivatized - MS/MS Non-kit	705	10.6	0.9	1.9	1.3	0.8
Non-derivatized - MS/MS Non-kit	118	11.0	1.3	2.0	1.3	0.9
Derivatized - MS/MS PE NeoGram MS2 Kit	284	10.4	0.9	1.1	1.3	0.8
Non-derivatized - MS/MS PE NeoGram MS2 Kit	46	10.1	0.9	1.4	1.2	0.8

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TYROSINE (mg Tyr/dL whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 821 – Nonenriched 0 mg/dL whole blood						
HPLC	50	1.3	0.1	0.2	1.4	0.9
Derivatized - MS/MS Non-kit	715	1.1	0.1	0.2	1.1	0.9
Non-derivatized - MS/MS Non-kit	148	1.2	0.1	0.4	1.1	1.0
Derivatized - MS/MS PE NeoGram MS2 Kit	286	1.1	0.1	0.2	1.1	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	69	1.2	0.1	0.2	1.1	1.0
Derivatized - MS/MS Chromsystems Kit	10	1.1	0.1	0.1	1.1	0.8
Lot 822 – Enriched 5 mg/dL whole blood						
HPLC	50	5.9	0.4	0.5	1.4	0.9
Derivatized - MS/MS Non-kit	712	5.4	0.5	1.0	1.1	0.9
Non-derivatized - MS/MS Non-kit	146	5.8	0.6	1.2	1.1	1.0
Derivatized - MS/MS PE NeoGram MS2 Kit	286	5.7	0.6	0.8	1.1	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	70	5.8	0.5	0.7	1.1	1.0
Derivatized - MS/MS Chromsystems Kit	10	5.1	0.5	0.5	1.1	0.8
Lot 823 – Enriched 9 mg/dL whole blood						
HPLC	49	9.8	0.6	0.9	1.4	0.9
Derivatized - MS/MS Non-kit	717	8.9	0.8	1.8	1.1	0.9
Non-derivatized - MS/MS Non-kit	149	9.9	0.8	2.3	1.1	1.0
Derivatized - MS/MS PE NeoGram MS2 Kit	281	9.3	0.8	1.2	1.1	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	68	10.0	0.6	1.2	1.1	1.0
Derivatized - MS/MS Chromsystems Kit	10	8.9	0.6	0.6	1.1	0.8
Lot 824 – Enriched 14 m/dL whole blood						
HPLC	50	13.9	1.0	1.5	1.4	0.9
Derivatized - MS/MS Non-kit	708	13.2	1.2	2.6	1.1	0.9
Non-derivatized - MS/MS Non-kit	150	14.6	1.3	3.2	1.1	1.0
Derivatized - MS/MS PE NeoGram MS2 Kit	285	13.9	1.3	1.9	1.1	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	70	14.8	1.2	1.8	1.1	1.0
Derivatized - MS/MS Chromsystems Kit	10	12.6	1.0	1.0	1.1	0.8

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7j. 2008 Quality Control Data
Summaries of Statistical Analyses

VALINE (mg Val/dL whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 725 – Nonenriched 0 mg/dL whole blood						
HPLC	20	2.6	0.2	0.2	2.7	0.9
Derivatized - MS/MS Non-kit	609	2.2	0.2	0.5	2.2	0.7
Non-derivatized - MS/MS Non-kit	60	1.8	0.3	0.4	1.7	0.6
Derivatized - MS/MS PE NeoGram MS2 Kit	268	1.9	0.2	0.3	1.9	0.7
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	2.0	0.2	0.2	1.9	0.7
Lot 726 – Enriched 3 mg/dL whole blood						
HPLC	20	5.2	0.3	0.4	2.7	0.9
Derivatized - MS/MS Non-kit	595	4.2	0.5	0.8	2.2	0.7
Non-derivatized - MS/MS Non-kit	59	3.4	0.3	0.5	1.7	0.6
Derivatized - MS/MS PE NeoGram MS2 Kit	266	3.8	0.5	0.6	1.9	0.7
Non-derivatized - MS/MS PE NeoGram MS2 Kit	42	3.9	0.3	0.4	1.9	0.7
Lot 727 – Enriched 7 mg/dL whole blood						
HPLC	19	9.2	0.4	0.5	2.7	0.9
Derivatized - MS/MS Non-kit	611	7.4	0.7	1.5	2.2	0.7
Non-derivatized - MS/MS Non-kit	58	6.0	0.5	0.7	1.7	0.6
Derivatized - MS/MS PE NeoGram MS2 Kit	266	6.6	0.7	1.0	1.9	0.7
Non-derivatized - MS/MS PE NeoGram MS2 Kit	41	6.7	0.4	0.4	1.9	0.7
Lot 728 – Enriched 11 mg/dL whole blood						
HPLC	20	11.8	0.5	1.1	2.7	0.9
Derivatized - MS/MS Non-kit	595	10.2	1.0	1.8	2.2	0.7
Non-derivatized - MS/MS Non-kit	59	8.6	0.8	1.3	1.7	0.6
Derivatized - MS/MS PE NeoGram MS2 Kit	262	9.1	1.1	1.5	1.9	0.7
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	9.7	0.8	0.9	1.9	0.7

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

VALINE (mg Val/dL whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 821 – Nonenriched 0 mg/dL whole blood						
HPLC	29	2.1	0.1	0.3	2.3	1.0
Derivatized - MS/MS Non-kit	632	2.0	0.2	0.4	2.0	0.8
Non-derivatized - MS/MS Non-kit	80	1.7	0.2	0.3	1.6	0.8
Derivatized - MS/MS PE NeoGram MS2 Kit	285	1.8	0.2	0.4	1.8	0.8
Non-derivatized - MS/MS PE NeoGram MS2 Kit	60	1.7	0.2	0.3	1.7	0.7
Derivatized - MS/MS Chromsystems Kit	10	1.6	0.1	0.1	1.7	0.7
Lot 822 – Enriched 3 mg/dL whole blood						
HPLC	30	5.3	0.3	0.6	2.3	1.0
Derivatized - MS/MS Non-kit	624	4.3	0.4	0.8	2.0	0.8
Non-derivatized - MS/MS Non-kit	80	3.8	0.4	0.6	1.6	0.8
Derivatized - MS/MS PE NeoGram MS2 Kit	290	4.1	0.5	0.9	1.8	0.8
Non-derivatized - MS/MS PE NeoGram MS2 Kit	59	3.9	0.3	0.7	1.7	0.7
Derivatized - MS/MS Chromsystems Kit	10	3.5	0.2	0.2	1.7	0.7
Lot 823 – Enriched 7 mg/dL whole blood						
HPLC	30	9.6	0.4	0.8	2.3	1.0
Derivatized - MS/MS Non-kit	623	7.5	0.7	1.4	2.0	0.8
Non-derivatized - MS/MS Non-kit	80	7.0	0.7	1.1	1.6	0.8
Derivatized - MS/MS PE NeoGram MS2 Kit	286	7.2	0.9	1.6	1.8	0.8
Non-derivatized - MS/MS PE NeoGram MS2 Kit	60	6.9	0.6	1.3	1.7	0.7
Derivatized - MS/MS Chromsystems Kit	10	6.5	0.3	0.3	1.7	0.7
Lot 824 – Enriched 11 mg/dL whole blood						
HPLC	30	12.6	1.0	1.6	2.3	1.0
Derivatized - MS/MS Non-kit	625	10.6	0.9	1.8	2.0	0.8
Non-derivatized - MS/MS Non-kit	80	10.0	1.0	1.6	1.6	0.8
Derivatized - MS/MS PE NeoGram MS2 Kit	287	10.1	1.1	2.2	1.8	0.8
Non-derivatized - MS/MS PE NeoGram MS2 Kit	60	9.9	0.7	1.7	1.7	0.7
Derivatized - MS/MS Chromsystems Kit	10	8.7	0.6	0.6	1.7	0.7

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7k. 2008 Quality Control Data
Summaries of Statistical Analyses

CITRULLINE (mg Cit/dL whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 725 – Nonenriched 0 mg/dL whole blood						
Derivatized - MS/MS Non-kit	610	0.4	0.1	0.1	0.4	0.7
Non-derivatized - MS/MS Non-kit	58	0.5	0.1	0.2	0.5	0.8
Derivatized - MS/MS PE NeoGram MS2 Kit	274	0.5	0.1	0.1	0.5	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	0.6	0.1	0.1	0.6	0.9
Lot 726 – Enriched 1 mg/dL whole blood						
Derivatized - MS/MS Non-kit	609	1.1	0.2	0.3	0.4	0.7
Non-derivatized - MS/MS Non-kit	59	1.2	0.2	0.3	0.5	0.8
Derivatized - MS/MS PE NeoGram MS2 Kit	270	1.5	0.1	0.2	0.5	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	1.5	0.2	0.4	0.6	0.9
Lot 727 – Enriched 3 mg/dL whole blood						
Derivatized - MS/MS Non-kit	607	2.5	0.3	0.6	0.4	0.7
Non-derivatized - MS/MS Non-kit	59	2.7	0.3	0.4	0.5	0.8
Derivatized - MS/MS PE NeoGram MS2 Kit	278	3.3	0.2	0.4	0.5	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	3.3	0.3	0.5	0.6	0.9
Lot 728 – Enriched 6 mg/dL whole blood						
Derivatized - MS/MS Non-kit	612	4.7	0.5	1.1	0.4	0.7
Non-derivatized - MS/MS Non-kit	59	5.1	0.7	1.0	0.5	0.8
Derivatized - MS/MS PE NeoGram MS2 Kit	273	6.0	0.5	0.8	0.5	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	5.9	0.6	0.7	0.6	0.9

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

CITRULLINE (mg Cit/dL whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 821 – Nonenriched 0 mg/dL whole blood						
Derivatized - MS/MS Non-kit	657	0.4	0.1	0.1	0.4	0.7
Non-derivatized - MS/MS Non-kit	85	0.5	0.1	0.2	0.4	0.8
Derivatized - MS/MS PE NeoGram MS2 Kit	287	0.5	0.1	0.1	0.5	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	60	0.5	0.1	0.1	0.5	1.0
Derivatized - MS/MS Chromsystems Kit	10	0.4	0.0	0.0	0.4	0.7
Lot 822 – Enriched 1 mg/dL whole blood						
Derivatized - MS/MS Non-kit	662	1.1	0.1	0.3	0.4	0.7
Non-derivatized - MS/MS Non-kit	85	1.2	0.2	0.3	0.4	0.8
Derivatized - MS/MS PE NeoGram MS2 Kit	288	1.4	0.1	0.2	0.5	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	57	1.5	0.2	0.3	0.5	1.0
Derivatized - MS/MS Chromsystems Kit	10	1.1	0.1	0.1	0.4	0.7
Lot 823 – Enriched 3 mg/dL whole blood						
Derivatized - MS/MS Non-kit	644	2.5	0.3	0.6	0.4	0.7
Non-derivatized - MS/MS Non-kit	87	3.0	0.4	0.8	0.4	0.8
Derivatized - MS/MS PE NeoGram MS2 Kit	286	3.3	0.3	0.4	0.5	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	56	3.7	0.3	0.7	0.5	1.0
Derivatized - MS/MS Chromsystems Kit	10	2.8	0.1	0.1	0.4	0.7
Lot 824 – Enriched 6 mg/dL whole blood						
Derivatized - MS/MS Non-kit	671	4.7	0.5	1.2	0.4	0.7
Non-derivatized - MS/MS Non-kit	86	5.2	0.5	1.1	0.4	0.8
Derivatized - MS/MS PE NeoGram MS2 Kit	279	6.0	0.4	0.7	0.5	0.9
Non-derivatized - MS/MS PE NeoGram MS2 Kit	60	6.7	0.5	1.0	0.5	1.0
Derivatized - MS/MS Chromsystems Kit	10	4.6	0.3	0.3	0.4	0.7

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7l. 2008 Quality Control Data
Summaries of Statistical Analyses

FREE CARNITINE (μmol C0/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 765 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	727	31.82	3.62	6.22	30.32	0.94
Non-derivatized MS/MS Non-kit	87	30.71	3.61	6.69	25.90	1.03
Derivatized - MS/MS PE NeoGram MS2 Kit	296	39.17	2.73	4.85	37.08	1.15
Non-derivatized - MS/MS PE NeoGram MS2 Kit	50	28.10	4.10	7.65	27.70	0.85
Lot 766 – Enriched 100 μmol/L whole blood						
Derivatized - MS/MS Non-kit	734	123.72	11.91	22.97	30.32	0.94
Non-derivatized MS/MS Non-kit	88	125.40	14.05	20.48	25.90	1.03
Derivatized - MS/MS PE NeoGram MS2 Kit	296	149.72	11.83	18.01	37.08	1.15
Non-derivatized - MS/MS PE NeoGram MS2 Kit	49	115.00	19.39	33.53	27.70	0.85
Lot 767 – Enriched 200 μmol/L whole blood						
Derivatized - MS/MS Non-kit	729	213.92	21.50	38.94	30.32	0.94
Non-derivatized MS/MS Non-kit	89	226.66	22.38	36.90	25.90	1.03
Derivatized - MS/MS PE NeoGram MS2 Kit	295	265.27	20.18	32.02	37.08	1.15
Non-derivatized - MS/MS PE NeoGram MS2 Kit	50	192.60	22.31	35.18	27.70	0.85
Lot 768 – Enriched 300 μmol/L whole blood						
Derivatized - MS/MS Non-kit	726	314.14	29.16	55.52	30.32	0.94
Non-derivatized MS/MS Non-kit	88	341.90	41.79	57.87	25.90	1.03
Derivatized - MS/MS PE NeoGram MS2 Kit	293	383.79	27.63	48.04	37.08	1.15
Non-derivatized - MS/MS PE NeoGram MS2 Kit	50	286.06	31.81	57.28	27.70	0.85

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

FREE CARNITINE (μmol C0/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 861 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	791	34.66	3.87	7.53	34.84	1.07
Non-derivatized MS/MS Non-kit	98	32.97	4.75	10.66	32.87	1.00
Derivatized - MS/MS PE NeoGram MS2 Kit	304	44.94	4.25	6.63	45.90	1.44
Non-derivatized - MS/MS PE NeoGram MS2 Kit	89	29.84	4.22	6.38	29.54	0.91
Derivatized-MS/MS Chromsystems Kit	10	40.70	3.47	3.47	38.67	1.26
Lot 862 – Enriched 50 μmol/L whole blood						
Derivatized - MS/MS Non-kit	790	88.20	8.42	18.16	34.84	1.07
Non-derivatized MS/MS Non-kit	98	81.96	9.39	24.04	32.87	1.00
Derivatized - MS/MS PE NeoGram MS2 Kit	307	118.52	10.93	17.42	45.90	1.44
Non-derivatized - MS/MS PE NeoGram MS2 Kit	89	74.65	8.88	14.41	29.54	0.91
Derivatized-MS/MS Chromsystems Kit	10	97.90	7.88	7.88	38.67	1.26
Lot 863 – Enriched 100 μmol/L whole blood						
Derivatized - MS/MS Non-kit	785	142.33	13.50	29.02	34.84	1.07
Non-derivatized MS/MS Non-kit	98	134.48	16.35	33.29	32.87	1.00
Derivatized - MS/MS PE NeoGram MS2 Kit	305	190.64	17.60	27.09	45.90	1.44
Non-derivatized - MS/MS PE NeoGram MS2 Kit	79	119.80	14.45	26.59	29.54	0.91
Derivatized-MS/MS Chromsystems Kit	10	165.20	13.58	13.58	38.67	1.26
Lot 864 – Enriched 150 μmol/L whole blood						
Derivatized - MS/MS Non-kit	789	194.66	19.42	39.39	34.84	1.07
Non-derivatized MS/MS Non-kit	98	182.18	21.15	46.11	32.87	1.00
Derivatized - MS/MS PE NeoGram MS2 Kit	306	260.18	24.58	35.84	45.90	1.44
Non-derivatized - MS/MS PE NeoGram MS2 Kit	79	165.99	21.13	34.26	29.54	0.91
Derivatized-MS/MS Chromsystems Kit	10	227.50	15.03	15.03	38.67	1.26

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7m. 2008 Quality Control Data
Summaries of Statistical Analyses

ACETYLCARNITINE (μmol C2/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 765 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	762	17.94	2.14	4.40	18.25	1.06
Non-derivatized MS/MS Non-kit	90	15.65	1.66	3.06	14.73	1.19
Derivatized - MS/MS PE NeoGram MS2 Kit	292	17.45	1.31	2.32	17.26	0.74
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	16.40	1.89	3.26	16.11	1.20
Lot 766 – Enriched 25 μmol/L whole blood						
Derivatized - MS/MS Non-kit	761	45.38	4.70	11.75	18.25	1.06
Non-derivatized MS/MS Non-kit	89	44.13	3.74	6.96	14.73	1.19
Derivatized - MS/MS PE NeoGram MS2 Kit	287	35.65	2.58	3.41	17.26	0.74
Non-derivatized - MS/MS PE NeoGram MS2 Kit	38	45.94	5.95	8.40	16.11	1.20
Lot 767 – Enriched 50 μmol/L whole blood						
Derivatized - MS/MS Non-kit	753	70.90	7.40	18.42	18.25	1.06
Non-derivatized MS/MS Non-kit	87	72.61	5.58	9.90	14.73	1.19
Derivatized - MS/MS PE NeoGram MS2 Kit	288	54.36	4.04	6.34	17.26	0.74
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	75.08	7.56	10.57	16.11	1.20
Lot 768 – Enriched 75 μmol/L whole blood						
Derivatized - MS/MS Non-kit	770	97.74	12.65	31.90	18.25	1.06
Non-derivatized MS/MS Non-kit	89	105.73	8.90	15.17	14.73	1.19
Derivatized - MS/MS PE NeoGram MS2 Kit	288	73.26	4.86	8.90	17.26	0.74
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	106.28	12.61	17.83	16.11	1.20

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

ACETYLCARNITINE (μmol C2/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 861 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	837	17.84	2.58	6.05	18.52	1.07
Non-derivatized MS/MS Non-kit	109	14.13	1.31	1.70	14.79	1.12
Derivatized - MS/MS PE NeoGram MS2 Kit	304	17.00	1.81	2.63	17.39	0.64
Non-derivatized - MS/MS PE NeoGram MS2 Kit	87	14.13	1.55	2.43	14.29	1.13
Derivatized-MS/MS Chromsystems Kit	10	13.78	1.45	1.45	13.00	1.01
Lot 862 – Enriched 25 μmol/L whole blood						
Derivatized - MS/MS Non-kit	796	45.89	4.89	11.73	18.52	1.07
Non-derivatized MS/MS Non-kit	109	43.93	4.54	5.03	14.79	1.12
Derivatized - MS/MS PE NeoGram MS2 Kit	294	33.71	2.86	3.60	17.39	0.64
Non-derivatized - MS/MS PE NeoGram MS2 Kit	85	43.34	3.37	6.79	14.29	1.13
Derivatized-MS/MS Chromsystems Kit	10	37.36	3.81	3.81	13.00	1.01
Lot 863 – Enriched 50 μmol/L whole blood						
Derivatized - MS/MS Non-kit	800	72.46	8.08	17.72	18.52	1.07
Non-derivatized MS/MS Non-kit	107	70.36	5.38	7.11	14.79	1.12
Derivatized - MS/MS PE NeoGram MS2 Kit	310	49.55	4.95	7.43	17.39	0.64
Non-derivatized - MS/MS PE NeoGram MS2 Kit	91	69.46	7.88	14.05	14.29	1.13
Derivatized-MS/MS Chromsystems Kit	10	63.20	5.94	5.94	13.00	1.01
Lot 864 – Enriched 75 μmol/L whole blood						
Derivatized - MS/MS Non-kit	836	97.77	12.40	30.26	18.52	1.07
Non-derivatized MS/MS Non-kit	108	98.54	6.98	10.75	14.79	1.12
Derivatized - MS/MS PE NeoGram MS2 Kit	290	64.69	5.53	7.71	17.39	0.64
Non-derivatized - MS/MS PE NeoGram MS2 Kit	88	99.34	9.01	16.76	14.29	1.13
Derivatized-MS/MS Chromsystems Kit	10	89.52	6.71	6.71	13.00	1.01

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7n. 2008 Quality Control Data
Summaries of Statistical Analyses

PROPIONYLCARNITINE (μmol C3/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 765 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	780	1.45	0.22	0.33	1.51	1.00
Non-derivatized MS/MS Non-kit	88	1.38	0.16	0.29	1.34	1.02
Derivatized - MS/MS PE NeoGram MS2 Kit	285	1.27	0.10	0.14	1.27	0.96
Non-derivatized - MS/MS PE NeoGram MS2 Kit	38	1.56	0.20	0.26	1.60	1.15
Lot 766 – Enriched 3 μmol/L whole blood						
Derivatized - MS/MS Non-kit	755	4.52	0.60	0.97	1.51	1.00
Non-derivatized MS/MS Non-kit	88	4.40	0.56	0.85	1.34	1.02
Derivatized - MS/MS PE NeoGram MS2 Kit	282	4.11	0.31	0.45	1.27	0.96
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	5.12	0.66	0.67	1.60	1.15
Lot 767 – Enriched 7.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	782	9.18	1.33	2.17	1.51	1.00
Non-derivatized MS/MS Non-kit	88	8.84	0.84	1.45	1.34	1.02
Derivatized - MS/MS PE NeoGram MS2 Kit	285	8.50	0.65	0.90	1.27	0.96
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	10.21	1.17	1.25	1.60	1.15
Lot 768 – Enriched 12 μmol/L whole blood						
Derivatized - MS/MS Non-kit	760	13.45	1.65	2.97	1.51	1.00
Non-derivatized MS/MS Non-kit	88	13.63	1.33	2.22	1.34	1.02
Derivatized - MS/MS PE NeoGram MS2 Kit	282	12.73	0.86	1.18	1.27	0.96
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	15.44	1.88	2.42	1.60	1.15

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PROPIONYLCARNITINE (μmol C3/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 861 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	842	1.60	0.27	0.52	1.81	1.10
Non-derivatized MS/MS Non-kit	108	1.49	0.20	0.26	1.70	1.04
Derivatized - MS/MS PE NeoGram MS2 Kit	308	1.28	0.13	0.16	1.33	0.95
Non-derivatized - MS/MS PE NeoGram MS2 Kit	78	1.44	0.21	0.30	1.49	1.10
Derivatized-MS/MS Chromsystems Kit	10	1.31	0.11	0.11	1.28	1.00
Lot 862 – Enriched 3 μmol/L whole blood						
Derivatized - MS/MS Non-kit	839	5.14	0.75	1.44	1.81	1.10
Non-derivatized MS/MS Non-kit	108	5.00	0.55	0.70	1.70	1.04
Derivatized - MS/MS PE NeoGram MS2 Kit	302	4.23	0.36	0.72	1.33	0.95
Non-derivatized - MS/MS PE NeoGram MS2 Kit	79	4.84	0.51	0.94	1.49	1.10
Derivatized-MS/MS Chromsystems Kit	10	4.22	0.23	0.23	1.28	1.00
Lot 863 – Enriched 7.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	849	10.60	1.64	4.58	1.81	1.10
Non-derivatized MS/MS Non-kit	109	9.67	0.93	1.41	1.70	1.04
Derivatized - MS/MS PE NeoGram MS2 Kit	310	8.48	0.82	1.31	1.33	0.95
Non-derivatized - MS/MS PE NeoGram MS2 Kit	79	9.75	1.01	2.02	1.49	1.10
Derivatized-MS/MS Chromsystems Kit	10	8.88	0.29	0.29	1.28	1.00
Lot 864 – Enriched 12 μmol/L whole blood						
Derivatized - MS/MS Non-kit	840	14.72	2.00	3.59	1.81	1.10
Non-derivatized MS/MS Non-kit	108	13.99	1.38	1.86	1.70	1.04
Derivatized - MS/MS PE NeoGram MS2 Kit	306	12.67	1.08	1.38	1.33	0.95
Non-derivatized - MS/MS PE NeoGram MS2 Kit	78	14.64	1.48	2.87	1.49	1.10
Derivatized-MS/MS Chromsystems Kit	10	13.30	0.82	0.82	1.28	1.00

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7o. 2008 Quality Control Data
Summaries of Statistical Analyses

MALONYLCARNITINE (μmol C3DC/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 765 – Assayed 0.08 μmol/L whole blood						
Derivatized - MS/MS Non-kit	569	0.06	0.03	0.04	-0.02	1.09
Non-derivatized MS/MS Non-kit	20	0.26	0.03	0.14	0.19	1.03
Derivatized - MS/MS PE NeoGram MS2 Kit	236	0.07	0.02	0.03	-0.08	2.45
Non-derivatized - MS/MS PE NeoGram MS2 Kit	30	0.39	0.09	0.30	0.19	2.18
Lot 766 – Assayed 0.19 μmol/L whole blood						
Derivatized - MS/MS Non-kit	571	0.19	0.05	0.10	-0.02	1.09
Non-derivatized MS/MS Non-kit	20	0.39	0.05	0.19	0.19	1.03
Derivatized - MS/MS PE NeoGram MS2 Kit	236	0.40	0.05	0.10	-0.08	2.45
Non-derivatized - MS/MS PE NeoGram MS2 Kit	30	0.60	0.12	0.41	0.19	2.18
Lot 767 – Assayed 0.44 μmol/L whole blood						
Derivatized - MS/MS Non-kit	570	0.48	0.09	0.22	-0.02	1.09
Non-derivatized MS/MS Non-kit	20	0.66	0.07	0.31	0.19	1.03
Derivatized - MS/MS PE NeoGram MS2 Kit	246	1.04	0.11	0.33	-0.08	2.45
Non-derivatized - MS/MS PE NeoGram MS2 Kit	30	1.12	0.18	0.84	0.19	2.18
Lot 768 – Assayed 0.76 μmol/L whole blood						
Derivatized - MS/MS Non-kit	575	0.80	0.17	0.37	-0.02	1.09
Non-derivatized MS/MS Non-kit	20	0.96	0.12	0.36	0.19	1.03
Derivatized - MS/MS PE NeoGram MS2 Kit	246	1.75	0.20	0.60	-0.08	2.45
Non-derivatized - MS/MS PE NeoGram MS2 Kit	30	1.87	0.22	1.32	0.19	2.18

Note that for both kit and non-kit users, the calculation of concentrations for the quality control lots varied with type of internal standard. Data are not sorted by internal standard type.

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

MALONYLCARNITINE (μmol C3DC/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 861 – Assayed 0.09 μmol/L whole blood						
Derivatized - MS/MS Non-kit	608	0.07	0.03	0.06	-0.01	1.06
Non-derivatized MS/MS Non-kit	50	0.19	0.04	0.12	0.15	0.62
Derivatized - MS/MS PE NeoGram MS2 Kit	238	0.09	0.02	0.05	-0.14	2.55
Non-derivatized - MS/MS PE NeoGram MS2 Kit	50	0.32	0.10	0.20	0.17	2.09
Derivatized-MS/MS Chromsystems Kit	10	0.08	0.01	0.01	-0.12	2.60
Lot 862 – Assayed 0.34 μmol/L whole blood						
Derivatized - MS/MS Non-kit	606	0.35	0.07	0.17	-0.01	1.06
Non-derivatized MS/MS Non-kit	50	0.35	0.07	0.19	0.15	0.62
Derivatized - MS/MS PE NeoGram MS2 Kit	248	0.75	0.13	0.30	-0.14	2.55
Non-derivatized - MS/MS PE NeoGram MS2 Kit	50	0.86	0.20	0.52	0.17	2.09
Derivatized-MS/MS Chromsystems Kit	10	0.74	0.03	0.03	-0.12	2.60
Lot 863 – Assayed 0.81 μmol/L whole blood						
Derivatized - MS/MS Non-kit	605	0.89	0.16	0.37	-0.01	1.06
Non-derivatized MS/MS Non-kit	50	0.69	0.13	0.38	0.15	0.62
Derivatized - MS/MS PE NeoGram MS2 Kit	243	1.88	0.22	0.68	-0.14	2.55
Non-derivatized - MS/MS PE NeoGram MS2 Kit	50	1.96	0.30	1.30	0.17	2.09
Derivatized-MS/MS Chromsystems Kit	10	2.11	0.11	0.11	-0.12	2.60
Lot 864 – Assayed 1.64 μmol/L whole blood						
Derivatized - MS/MS Non-kit	605	1.71	0.31	0.75	-0.01	1.06
Non-derivatized MS/MS Non-kit	50	1.15	0.19	0.59	0.15	0.62
Derivatized - MS/MS PE NeoGram MS2 Kit	238	4.06	0.57	2.09	-0.14	2.55
Non-derivatized - MS/MS PE NeoGram MS2 Kit	50	3.55	0.39	2.31	0.17	2.09
Derivatized-MS/MS Chromsystems Kit	10	4.10	0.34	0.34	-0.12	2.60

Note that for both kit and non-kit users, the calculation of concentrations for the quality control lots varied with type of internal standard. Data are not sorted by internal standard type.

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7p. 2008 Quality Control Data
Summaries of Statistical Analyses

BUTYRYLCARNITINE (μmol C4/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 765 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	749	0.24	0.06	0.08	0.24	0.90
Non-derivatized MS/MS Non-kit	88	0.29	0.11	0.20	0.27	0.89
Derivatized - MS/MS PE NeoGram MS2 Kit	271	0.21	0.05	0.06	0.20	0.79
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	0.26	0.09	0.09	0.21	0.89
Lot 766 – Enriched 1 μmol/L whole blood						
Derivatized - MS/MS Non-kit	759	1.16	0.17	0.25	0.24	0.90
Non-derivatized MS/MS Non-kit	89	1.18	0.15	0.25	0.27	0.89
Derivatized - MS/MS PE NeoGram MS2 Kit	271	1.00	0.16	0.17	0.20	0.79
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	1.08	0.25	0.29	0.21	0.89
Lot 767 – Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	732	2.47	0.28	0.43	0.24	0.90
Non-derivatized MS/MS Non-kit	87	2.44	0.21	0.54	0.27	0.89
Derivatized - MS/MS PE NeoGram MS2 Kit	275	2.17	0.35	0.40	0.20	0.79
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	2.36	0.49	0.54	0.21	0.89
Lot 768 – Enriched 5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	745	4.75	0.56	0.85	0.24	0.90
Non-derivatized MS/MS Non-kit	89	4.77	0.56	1.25	0.27	0.89
Derivatized - MS/MS PE NeoGram MS2 Kit	271	4.17	0.64	0.72	0.20	0.79
Non-derivatized - MS/MS PE NeoGram MS2 Kit	38	4.69	0.67	0.67	0.21	0.89

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

BUTYRYLCARNITINE (μmol C4/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 861 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	796	0.29	0.12	0.23	0.31	1.01
Non-derivatized MS/MS Non-kit	105	0.21	0.05	0.12	0.28	0.88
Derivatized - MS/MS PE NeoGram MS2 Kit	296	0.21	0.06	0.08	0.24	0.82
Non-derivatized - MS/MS PE NeoGram MS2 Kit	76	0.24	0.07	0.10	0.25	0.93
Derivatized-MS/MS Chromsystems Kit	10	0.15	0.01	0.01	0.10	0.77
Lot 862 – Enriched 1 μmol/L whole blood						
Derivatized - MS/MS Non-kit	778	1.34	0.18	0.27	0.31	1.01
Non-derivatized MS/MS Non-kit	109	1.22	0.13	0.20	0.28	0.88
Derivatized - MS/MS PE NeoGram MS2 Kit	290	1.09	0.20	0.25	0.24	0.82
Non-derivatized - MS/MS PE NeoGram MS2 Kit	77	1.23	0.21	0.23	0.25	0.93
Derivatized-MS/MS Chromsystems Kit	10	0.84	0.04	0.04	0.10	0.77
Lot 863 – Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	783	2.86	0.35	0.55	0.31	1.01
Non-derivatized MS/MS Non-kit	109	2.54	0.28	0.37	0.28	0.88
Derivatized - MS/MS PE NeoGram MS2 Kit	298	2.29	0.37	0.56	0.24	0.82
Non-derivatized - MS/MS PE NeoGram MS2 Kit	77	2.55	0.43	0.50	0.25	0.93
Derivatized-MS/MS Chromsystems Kit	10	1.98	0.13	0.13	0.10	0.77
Lot 864 – Enriched 5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	783	5.36	0.59	0.91	0.31	1.01
Non-derivatized MS/MS Non-kit	109	4.66	0.47	0.67	0.28	0.88
Derivatized - MS/MS PE NeoGram MS2 Kit	281	4.31	0.68	0.85	0.24	0.82
Non-derivatized - MS/MS PE NeoGram MS2 Kit	76	4.94	0.58	0.71	0.25	0.93
Derivatized-MS/MS Chromsystems Kit	10	3.99	0.19	0.19	0.10	0.77

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7q. 2008 Quality Control Data
Summaries of Statistical Analyses

ISOVALERYLCARNITINE (μmol C5/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 765 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	735	0.13	0.03	0.04	0.14	0.93
Non-derivatized MS/MS Non-kit	89	0.11	0.02	0.03	0.11	0.95
Derivatized - MS/MS PE NeoGram MS2 Kit	283	0.13	0.03	0.04	0.14	0.90
Non-derivatized - MS/MS PE NeoGram MS2 Kit	29	0.13	0.05	0.06	0.13	0.80
Lot 766 – Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	735	0.63	0.09	0.13	0.14	0.93
Non-derivatized MS/MS Non-kit	88	0.59	0.07	0.08	0.11	0.95
Derivatized - MS/MS PE NeoGram MS2 Kit	281	0.60	0.09	0.09	0.14	0.90
Non-derivatized - MS/MS PE NeoGram MS2 Kit	29	0.54	0.12	0.13	0.13	0.80
Lot 767 – Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	734	1.52	0.18	0.29	0.14	0.93
Non-derivatized MS/MS Non-kit	89	1.50	0.16	0.20	0.11	0.95
Derivatized - MS/MS PE NeoGram MS2 Kit	283	1.51	0.22	0.24	0.14	0.90
Non-derivatized - MS/MS PE NeoGram MS2 Kit	29	1.32	0.31	0.40	0.13	0.80
Lot 768 – Enriched 3 μmol/L whole blood						
Derivatized - MS/MS Non-kit	730	2.92	0.33	0.56	0.14	0.93
Non-derivatized MS/MS Non-kit	90	2.96	0.35	0.44	0.11	0.95
Derivatized - MS/MS PE NeoGram MS2 Kit	287	2.84	0.40	0.45	0.14	0.90
Non-derivatized - MS/MS PE NeoGram MS2 Kit	29	2.55	0.46	0.70	0.13	0.80

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

ISOVALERYLCARNITINE (μmol C5/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 861 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	825	0.16	0.04	0.06	0.17	0.99
Non-derivatized MS/MS Non-kit	106	0.12	0.03	0.04	0.13	0.95
Derivatized - MS/MS PE NeoGram MS2 Kit	308	0.14	0.04	0.05	0.15	0.89
Non-derivatized - MS/MS PE NeoGram MS2 Kit	86	0.13	0.03	0.04	0.13	0.87
Derivatized-MS/MS Chromsystems Kit	10	0.12	0.01	0.01	0.10	0.96
Lot 862 – Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	836	0.68	0.09	0.17	0.17	0.99
Non-derivatized MS/MS Non-kit	109	0.61	0.08	0.13	0.13	0.95
Derivatized - MS/MS PE NeoGram MS2 Kit	298	0.60	0.11	0.12	0.15	0.89
Non-derivatized - MS/MS PE NeoGram MS2 Kit	87	0.56	0.10	0.12	0.13	0.87
Derivatized-MS/MS Chromsystems Kit	10	0.56	0.03	0.03	0.10	0.96
Lot 863 – Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	839	1.68	0.26	0.41	0.17	0.99
Non-derivatized MS/MS Non-kit	108	1.57	0.14	0.25	0.13	0.95
Derivatized - MS/MS PE NeoGram MS2 Kit	300	1.51	0.22	0.29	0.15	0.89
Non-derivatized - MS/MS PE NeoGram MS2 Kit	88	1.45	0.20	0.26	0.13	0.87
Derivatized-MS/MS Chromsystems Kit	10	1.53	0.09	0.09	0.10	0.96
Lot 864 – Enriched 3 μmol/L whole blood						
Derivatized - MS/MS Non-kit	826	3.12	0.35	0.61	0.17	0.99
Non-derivatized MS/MS Non-kit	108	2.96	0.28	0.45	0.13	0.95
Derivatized - MS/MS PE NeoGram MS2 Kit	297	2.80	0.40	0.46	0.15	0.89
Non-derivatized - MS/MS PE NeoGram MS2 Kit	88	2.73	0.40	0.53	0.13	0.87
Derivatized-MS/MS Chromsystems Kit	10	3.00	0.18	0.18	0.10	0.96

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7r. 2008 Quality Control Data
Summaries of Statistical Analyses

GLUTARYLCARNITINE (μmol C5DC/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 765 – Assayed 0.03 μmol/L whole blood						
Derivatized - MS/MS Non-kit	752	0.04	0.02	0.02	0.03	1.10
Non-derivatized MS/MS Non-kit	78	0.07	0.02	0.05	0.04	1.64
Derivatized - MS/MS PE NeoGram MS2 Kit	284	0.07	0.01	0.02	0.03	2.74
Non-derivatized - MS/MS PE NeoGram MS2 Kit	38	0.17	0.10	0.12	-0.05	4.26
Lot 766 – Assayed 0.36 μmol/L whole blood						
Derivatized - MS/MS Non-kit	749	0.43	0.07	0.14	0.03	1.10
Non-derivatized MS/MS Non-kit	78	0.63	0.09	0.45	0.04	1.64
Derivatized - MS/MS PE NeoGram MS2 Kit	271	1.04	0.10	0.16	0.03	2.74
Non-derivatized - MS/MS PE NeoGram MS2 Kit	33	1.57	0.49	0.97	-0.05	4.26
Lot 767 – Assayed 0.74 μmol/L whole blood						
Derivatized - MS/MS Non-kit	750	0.86	0.14	0.28	0.03	1.10
Non-derivatized MS/MS Non-kit	74	1.28	0.15	0.92	0.04	1.64
Derivatized - MS/MS PE NeoGram MS2 Kit	278	2.12	0.20	0.33	0.03	2.74
Non-derivatized - MS/MS PE NeoGram MS2 Kit	45	2.84	0.85	1.74	-0.05	4.26
Lot 768 – Assayed 1.47 μmol/L whole blood						
Derivatized - MS/MS Non-kit	749	1.62	0.24	0.53	0.03	1.10
Non-derivatized MS/MS Non-kit	82	2.44	0.43	1.74	0.04	1.64
Derivatized - MS/MS PE NeoGram MS2 Kit	272	4.03	0.32	0.59	0.03	2.74
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	6.34	1.35	3.57	-0.05	4.26

Note that for both kit and non-kit users, the calculation of concentrations for the quality control lots varied with type of internal standard. Data are not sorted by internal standard type. In a survey, participants reported using d9-C5, d3-C8, d3-C10, d3-C12, d3-C16, or d6-C5DC as an internal standard for C5DC.

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

GLUTARYLCARNITINE (μmol C5DC/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 861 – Assayed 0.08 μmol/L whole blood						
Derivatized - MS/MS Non-kit	826	0.05	0.02	0.03	-0.04	1.12
Non-derivatized MS/MS Non-kit	107	0.08	0.02	0.05	-0.04	1.61
Derivatized - MS/MS PE NeoGram MS2 Kit	299	0.07	0.02	0.02	-0.13	2.53
Non-derivatized - MS/MS PE NeoGram MS2 Kit	87	0.17	0.07	0.13	-0.10	3.43
Derivatized-MS/MS Chromsystems Kit	10	0.08	0.01	0.01	-0.17	2.82
Lot 862 – Assayed 0.35 μmol/L whole blood						
Derivatized - MS/MS Non-kit	816	0.35	0.06	0.12	-0.04	1.12
Non-derivatized MS/MS Non-kit	109	0.50	0.09	0.28	-0.04	1.61
Derivatized - MS/MS PE NeoGram MS2 Kit	299	0.72	0.07	0.23	-0.13	2.53
Non-derivatized - MS/MS PE NeoGram MS2 Kit	88	1.11	0.17	0.65	-0.10	3.43
Derivatized-MS/MS Chromsystems Kit	10	0.75	0.05	0.05	-0.17	2.82
Lot 863 – Assayed 0.59 μmol/L whole blood						
Derivatized - MS/MS Non-kit	828	0.65	0.12	0.23	-0.04	1.12
Non-derivatized MS/MS Non-kit	110	0.95	0.16	0.54	-0.04	1.61
Derivatized - MS/MS PE NeoGram MS2 Kit	306	1.40	0.15	0.35	-0.13	2.53
Non-derivatized - MS/MS PE NeoGram MS2 Kit	86	1.92	0.25	1.19	-0.10	3.43
Derivatized-MS/MS Chromsystems Kit	10	1.53	0.10	0.10	-0.17	2.82
Lot 864 – Assayed 1.13 μmol/L whole blood						
Derivatized - MS/MS Non-kit	822	1.22	0.18	0.40	-0.04	1.12
Non-derivatized MS/MS Non-kit	110	1.77	0.27	0.99	-0.04	1.61
Derivatized - MS/MS PE NeoGram MS2 Kit	295	2.71	0.27	0.66	-0.13	2.53
Non-derivatized - MS/MS PE NeoGram MS2 Kit	88	3.77	0.60	2.43	-0.10	3.43
Derivatized-MS/MS Chromsystems Kit	10	3.01	0.23	0.23	-0.17	2.82

Note that for both kit and non-kit users, the calculation of concentrations for the quality control lots varied with type of internal standard. Data are not sorted by internal standard type. In a survey, participants reported using d9-C5, d3-C8, d3-C10, d3-C12, d3-C16, or d6-C5DC as an internal standard for C5DC.

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7s. 2008 Quality Control Data
Summaries of Statistical Analyses

HEXANOYLCARNITINE (μmol C6/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 765 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	798	0.07	0.03	0.05	0.07	0.83
Non-derivatized MS/MS Non-kit	74	0.04	0.02	0.03	0.03	0.97
Derivatized - MS/MS PE NeoGram MS2 Kit	289	0.05	0.03	0.04	0.07	0.80
Non-derivatized - MS/MS PE NeoGram MS2 Kit	38	0.03	0.01	0.03	0.04	0.94
Lot 766 – Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	798	0.49	0.08	0.13	0.07	0.83
Non-derivatized MS/MS Non-kit	76	0.52	0.07	0.11	0.03	0.97
Derivatized - MS/MS PE NeoGram MS2 Kit	286	0.48	0.09	0.10	0.07	0.80
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	0.51	0.06	0.07	0.04	0.94
Lot 767 – Enriched 1 μmol/L whole blood						
Derivatized - MS/MS Non-kit	800	0.90	0.14	0.23	0.07	0.83
Non-derivatized MS/MS Non-kit	76	0.96	0.10	0.17	0.03	0.97
Derivatized - MS/MS PE NeoGram MS2 Kit	282	0.88	0.14	0.16	0.07	0.80
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	0.99	0.10	0.12	0.04	0.94
Lot 768 – Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	795	2.14	0.26	0.52	0.07	0.83
Non-derivatized MS/MS Non-kit	76	2.46	0.22	0.45	0.03	0.97
Derivatized - MS/MS PE NeoGram MS2 Kit	284	2.06	0.28	0.33	0.07	0.80
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	2.39	0.19	0.23	0.04	0.94

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

HEXANOYLCARNITINE (μmol C6/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 861 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	835	0.08	0.03	0.05	0.09	0.89
Non-derivatized MS/MS Non-kit	94	0.05	0.02	0.05	0.08	0.96
Derivatized - MS/MS PE NeoGram MS2 Kit	292	0.06	0.03	0.03	0.07	0.77
Non-derivatized - MS/MS PE NeoGram MS2 Kit	88	0.04	0.01	0.02	0.05	0.95
Derivatized-MS/MS Chromsystems Kit	10	0.06	0.01	0.01	0.05	0.83
Lot 862 – Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	833	0.54	0.08	0.14	0.09	0.89
Non-derivatized MS/MS Non-kit	99	0.58	0.08	0.14	0.08	0.96
Derivatized - MS/MS PE NeoGram MS2 Kit	297	0.46	0.11	0.14	0.07	0.77
Non-derivatized - MS/MS PE NeoGram MS2 Kit	86	0.53	0.05	0.09	0.05	0.95
Derivatized-MS/MS Chromsystems Kit	10	0.45	0.04	0.04	0.05	0.83
Lot 863 – Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	826	1.00	0.15	0.24	0.09	0.89
Non-derivatized MS/MS Non-kit	99	1.07	0.10	0.19	0.08	0.96
Derivatized - MS/MS PE NeoGram MS2 Kit	292	0.84	0.15	0.18	0.07	0.77
Non-derivatized - MS/MS PE NeoGram MS2 Kit	85	1.00	0.08	0.15	0.05	0.95
Derivatized-MS/MS Chromsystems Kit	10	0.88	0.04	0.04	0.05	0.83
Lot 864 – Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	831	2.31	0.28	0.52	0.09	0.89
Non-derivatized MS/MS Non-kit	99	2.47	0.22	0.38	0.08	0.96
Derivatized - MS/MS PE NeoGram MS2 Kit	285	1.98	0.30	0.35	0.07	0.77
Non-derivatized - MS/MS PE NeoGram MS2 Kit	88	2.42	0.20	0.36	0.05	0.95
Derivatized-MS/MS Chromsystems Kit	10	2.14	0.10	0.10	0.05	0.83

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7t. 2008 Quality Control Data
Summaries of Statistical Analyses

OCTANOYLCARNITINE (μmol C8/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 765 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	809	0.11	0.07	0.10	0.12	1.01
Non-derivatized MS/MS Non-kit	109	0.11	0.02	0.06	0.11	1.03
Derivatized - MS/MS PE NeoGram MS2 Kit	283	0.09	0.03	0.04	0.10	0.91
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	0.10	0.06	0.08	0.09	1.01
Lot 766 – Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	796	0.62	0.09	0.11	0.12	1.01
Non-derivatized MS/MS Non-kit	106	0.62	0.08	0.11	0.11	1.03
Derivatized - MS/MS PE NeoGram MS2 Kit	286	0.56	0.10	0.11	0.10	0.91
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	0.61	0.15	0.19	0.09	1.01
Lot 767 – Enriched 1 μmol/L whole blood						
Derivatized - MS/MS Non-kit	798	1.13	0.14	0.19	0.12	1.01
Non-derivatized MS/MS Non-kit	107	1.13	0.11	0.16	0.11	1.03
Derivatized - MS/MS PE NeoGram MS2 Kit	283	1.00	0.15	0.16	0.10	0.91
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	1.09	0.16	0.19	0.09	1.01
Lot 768 – Enriched2.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	800	2.64	0.29	0.44	0.12	1.01
Non-derivatized MS/MS Non-kit	110	2.67	0.24	0.30	0.11	1.03
Derivatized - MS/MS PE NeoGram MS2 Kit	287	2.37	0.32	0.37	0.10	0.91
Non-derivatized - MS/MS PE NeoGram MS2 Kit	42	2.64	0.53	0.60	0.09	1.01

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

OCTANOYLCARNITINE (μmol C8/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 861 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	820	0.14	0.03	0.05	0.17	1.07
Non-derivatized MS/MS Non-kit	139	0.14	0.03	0.05	0.17	1.05
Derivatized - MS/MS PE NeoGram MS2 Kit	304	0.12	0.04	0.05	0.14	0.87
Non-derivatized - MS/MS PE NeoGram MS2 Kit	88	0.13	0.03	0.05	0.15	1.00
Derivatized-MS/MS Chromsystems Kit	10	0.09	0.01	0.01	0.08	0.71
Lot 862 – Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	824	0.72	0.10	0.17	0.17	1.07
Non-derivatized MS/MS Non-kit	137	0.72	0.09	0.13	0.17	1.05
Derivatized - MS/MS PE NeoGram MS2 Kit	296	0.60	0.12	0.13	0.14	0.87
Non-derivatized - MS/MS PE NeoGram MS2 Kit	88	0.66	0.09	0.12	0.15	1.00
Derivatized-MS/MS Chromsystems Kit	10	0.44	0.05	0.05	0.08	0.71
Lot 863 – Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	835	1.27	0.20	0.31	0.17	1.07
Non-derivatized MS/MS Non-kit	136	1.25	0.12	0.18	0.17	1.05
Derivatized - MS/MS PE NeoGram MS2 Kit	302	1.01	0.18	0.20	0.14	0.87
Non-derivatized - MS/MS PE NeoGram MS2 Kit	88	1.16	0.13	0.21	0.15	1.00
Derivatized-MS/MS Chromsystems Kit	10	0.77	0.05	0.05	0.08	0.71
Lot 864 – Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	828	2.84	0.34	0.60	0.17	1.07
Non-derivatized MS/MS Non-kit	138	2.80	0.23	0.41	0.17	1.05
Derivatized - MS/MS PE NeoGram MS2 Kit	302	2.30	0.35	0.39	0.14	0.87
Non-derivatized - MS/MS PE NeoGram MS2 Kit	87	2.64	0.31	0.39	0.15	1.00
Derivatized-MS/MS Chromsystems Kit	10	1.87	0.11	0.11	0.08	0.71

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7u. 2008 Quality Control Data
Summaries of Statistical Analyses

DECANOYLCARNITINE (μmol C10/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 765 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	773	0.13	0.03	0.05	0.11	1.39
Non-derivatized MS/MS Non-kit	96	0.12	0.02	0.06	0.09	1.28
Derivatized - MS/MS PE NeoGram MS2 Kit	286	0.09	0.03	0.03	0.08	0.91
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	0.09	0.02	0.03	0.07	1.06
Lot 766 – Enriched 0.25 μmol/L whole blood						
Derivatized - MS/MS Non-kit	774	0.45	0.07	0.11	0.11	1.39
Non-derivatized MS/MS Non-kit	98	0.42	0.05	0.08	0.09	1.28
Derivatized - MS/MS PE NeoGram MS2 Kit	280	0.31	0.06	0.07	0.08	0.91
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	0.33	0.07	0.10	0.07	1.06
Lot 767 – Enriched 0.75 μmol/L whole blood						
Derivatized - MS/MS Non-kit	787	1.12	0.19	0.28	0.11	1.39
Non-derivatized MS/MS Non-kit	98	0.97	0.10	0.14	0.09	1.28
Derivatized - MS/MS PE NeoGram MS2 Kit	289	0.76	0.12	0.16	0.08	0.91
Non-derivatized - MS/MS PE NeoGram MS2 Kit	38	0.82	0.12	0.16	0.07	1.06
Lot 768 – Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	777	2.21	0.30	0.49	0.11	1.39
Non-derivatized MS/MS Non-kit	98	2.04	0.20	0.30	0.09	1.28
Derivatized - MS/MS PE NeoGram MS2 Kit	281	1.45	0.20	0.27	0.08	0.91
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	1.68	0.38	0.57	0.07	1.06

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

DECANOYLCARNITINE (μmol C10/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 861 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	806	0.18	0.04	0.07	0.19	1.27
Non-derivatized MS/MS Non-kit	117	0.20	0.03	0.10	0.22	1.12
Derivatized - MS/MS PE NeoGram MS2 Kit	303	0.12	0.04	0.04	0.13	0.76
Non-derivatized - MS/MS PE NeoGram MS2 Kit	87	0.14	0.03	0.04	0.15	0.94
Derivatized-MS/MS Chromsystems Kit	10	0.14	0.02	0.02	0.13	0.86
Lot 862 – Enriched 0.25 μmol/L whole blood						
Derivatized - MS/MS Non-kit	812	0.51	0.08	0.14	0.19	1.27
Non-derivatized MS/MS Non-kit	116	0.51	0.06	0.14	0.22	1.12
Derivatized - MS/MS PE NeoGram MS2 Kit	302	0.32	0.07	0.09	0.13	0.76
Non-derivatized - MS/MS PE NeoGram MS2 Kit	85	0.40	0.08	0.10	0.15	0.94
Derivatized-MS/MS Chromsystems Kit	10	0.33	0.03	0.03	0.13	0.86
Lot 863 – Enriched 0.75 μmol/L whole blood						
Derivatized - MS/MS Non-kit	819	1.15	0.17	0.30	0.19	1.27
Non-derivatized MS/MS Non-kit	115	1.08	0.11	0.28	0.22	1.12
Derivatized - MS/MS PE NeoGram MS2 Kit	308	0.71	0.12	0.18	0.13	0.76
Non-derivatized - MS/MS PE NeoGram MS2 Kit	88	0.86	0.10	0.14	0.15	0.94
Derivatized-MS/MS Chromsystems Kit	10	0.75	0.04	0.04	0.13	0.86
Lot 864 – Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	829	2.08	0.31	0.56	0.19	1.27
Non-derivatized MS/MS Non-kit	115	1.89	0.18	0.49	0.22	1.12
Derivatized - MS/MS PE NeoGram MS2 Kit	291	1.26	0.20	0.23	0.13	0.76
Non-derivatized - MS/MS PE NeoGram MS2 Kit	86	1.55	0.18	0.22	0.15	0.94
Derivatized-MS/MS Chromsystems Kit	10	1.42	0.10	0.10	0.13	0.86

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7v. 2008 Quality Control Data
Summaries of Statistical Analyses

MYRISTOYLCARNITINE (μmol C14/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 765 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	757	0.10	0.03	0.04	0.13	1.07
Non-derivatized MS/MS Non-kit	78	0.08	0.02	0.03	0.08	1.07
Derivatized - MS/MS PE NeoGram MS2 Kit	287	0.09	0.03	0.03	0.13	0.91
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	0.07	0.03	0.04	0.07	0.80
Lot 766 – Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	747	0.66	0.10	0.15	0.13	1.07
Non-derivatized MS/MS Non-kit	80	0.61	0.07	0.10	0.08	1.07
Derivatized - MS/MS PE NeoGram MS2 Kit	289	0.58	0.09	0.11	0.13	0.91
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	0.46	0.11	0.18	0.07	0.80
Lot 767 – Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	748	1.80	0.23	0.38	0.13	1.07
Non-derivatized MS/MS Non-kit	78	1.72	0.16	0.29	0.08	1.07
Derivatized - MS/MS PE NeoGram MS2 Kit	292	1.57	0.22	0.25	0.13	0.91
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	1.29	0.16	0.34	0.07	0.80
Lot 768 – Enriched 3 μmol/L whole blood						
Derivatized - MS/MS Non-kit	754	3.30	0.43	0.72	0.13	1.07
Non-derivatized MS/MS Non-kit	80	3.28	0.32	0.55	0.08	1.07
Derivatized - MS/MS PE NeoGram MS2 Kit	292	2.81	0.33	0.38	0.13	0.91
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	2.46	0.30	0.75	0.07	0.80

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

MYRISTOYLCARNITINE (μmol C14/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 861 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	806	0.13	0.04	0.06	0.15	1.03
Non-derivatized MS/MS Non-kit	108	0.12	0.03	0.06	0.12	1.04
Derivatized - MS/MS PE NeoGram MS2 Kit	290	0.09	0.03	0.03	0.12	0.80
Non-derivatized - MS/MS PE NeoGram MS2 Kit	86	0.07	0.02	0.03	0.07	0.72
Derivatized-MS/MS Chromsystems Kit	10	0.08	0.01	0.01	0.06	0.64
Lot 862 – Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	808	0.66	0.10	0.16	0.15	1.03
Non-derivatized MS/MS Non-kit	109	0.63	0.08	0.13	0.12	1.04
Derivatized - MS/MS PE NeoGram MS2 Kit	283	0.51	0.09	0.13	0.12	0.80
Non-derivatized - MS/MS PE NeoGram MS2 Kit	87	0.43	0.05	0.10	0.07	0.72
Derivatized-MS/MS Chromsystems Kit	10	0.37	0.02	0.02	0.06	0.64
Lot 863 – Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	806	1.74	0.23	0.36	0.15	1.03
Non-derivatized MS/MS Non-kit	108	1.73	0.18	0.28	0.12	1.04
Derivatized - MS/MS PE NeoGram MS2 Kit	288	1.38	0.20	0.24	0.12	0.80
Non-derivatized - MS/MS PE NeoGram MS2 Kit	88	1.17	0.13	0.29	0.07	0.72
Derivatized-MS/MS Chromsystems Kit	10	1.01	0.05	0.05	0.06	0.64
Lot 864 – Enriched 3 μmol/L whole blood						
Derivatized - MS/MS Non-kit	807	3.22	0.43	0.66	0.15	1.03
Non-derivatized MS/MS Non-kit	110	3.23	0.26	0.56	0.12	1.04
Derivatized - MS/MS PE NeoGram MS2 Kit	282	2.49	0.34	0.43	0.12	0.80
Non-derivatized - MS/MS PE NeoGram MS2 Kit	88	2.24	0.22	0.61	0.07	0.72
Derivatized-MS/MS Chromsystems Kit	10	2.00	0.12	0.12	0.06	0.64

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7w. 2008 Quality Control Data
Summaries of Statistical Analyses

PALMITOYLCARNITINE (μmol C16/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 765 – Enriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	775	0.91	0.16	0.20	1.02	0.85
Non-derivatized MS/MS Non-kit	90	0.91	0.11	0.16	0.97	0.92
Derivatized - MS/MS PE NeoGram MS2 Kit	285	0.91	0.14	0.15	1.02	0.83
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	0.90	0.14	0.16	1.01	0.89
Lot 766 – Enriched 4 μmol/L whole blood						
Derivatized - MS/MS Non-kit	765	4.49	0.52	0.75	1.02	0.85
Non-derivatized MS/MS Non-kit	90	4.62	0.41	0.69	0.97	0.92
Derivatized - MS/MS PE NeoGram MS2 Kit	286	4.37	0.51	0.60	1.02	0.83
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	4.65	0.63	0.63	1.01	0.89
Lot 767 – Enriched 8 μmol/L whole blood						
Derivatized - MS/MS Non-kit	761	8.02	0.85	1.27	1.02	0.85
Non-derivatized MS/MS Non-kit	89	8.51	0.79	1.37	0.97	0.92
Derivatized - MS/MS PE NeoGram MS2 Kit	282	7.91	0.84	1.00	1.02	0.83
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	8.27	0.70	0.79	1.01	0.89
Lot 768 – Enriched 12 μmol/L whole blood						
Derivatized - MS/MS Non-kit	789	11.10	1.44	2.28	1.02	0.85
Non-derivatized MS/MS Non-kit	89	11.83	1.03	1.86	0.97	0.92
Derivatized - MS/MS PE NeoGram MS2 Kit	288	10.74	1.12	1.40	1.02	0.83
Non-derivatized - MS/MS PE NeoGram MS2 Kit	38	11.52	0.98	1.07	1.01	0.89

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PALMITOYLCARNITINE (μmol C16/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 861 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	825	1.11	0.17	0.23	1.12	0.94
Non-derivatized MS/MS Non-kit	99	1.02	0.14	0.16	1.02	0.88
Derivatized - MS/MS PE NeoGram MS2 Kit	286	1.01	0.15	0.17	1.02	0.85
Non-derivatized - MS/MS PE NeoGram MS2 Kit	87	1.04	0.14	0.18	0.97	0.92
Derivatized-MS/MS Chromsystems Kit	10	0.76	0.06	0.06	0.64	0.67
Lot 862 – Enriched 4 μmol/L whole blood						
Derivatized - MS/MS Non-kit	833	4.83	0.52	0.89	1.12	0.94
Non-derivatized MS/MS Non-kit	99	4.47	0.48	0.65	1.02	0.88
Derivatized - MS/MS PE NeoGram MS2 Kit	279	4.42	0.56	0.65	1.02	0.85
Non-derivatized - MS/MS PE NeoGram MS2 Kit	88	4.63	0.44	0.65	0.97	0.92
Derivatized-MS/MS Chromsystems Kit	10	3.20	0.25	0.25	0.64	0.67
Lot 863 – Enriched 8 μmol/L whole blood						
Derivatized - MS/MS Non-kit	825	8.66	0.91	1.50	1.12	0.94
Non-derivatized MS/MS Non-kit	100	8.27	0.74	1.12	1.02	0.88
Derivatized - MS/MS PE NeoGram MS2 Kit	285	7.86	1.02	1.35	1.02	0.85
Non-derivatized - MS/MS PE NeoGram MS2 Kit	88	8.25	0.82	1.21	0.97	0.92
Derivatized-MS/MS Chromsystems Kit	10	5.91	0.34	0.34	0.64	0.67
Lot 864 – Enriched 12 μmol/L whole blood						
Derivatized - MS/MS Non-kit	832	12.31	1.33	2.21	1.12	0.94
Non-derivatized MS/MS Non-kit	98	11.55	0.99	1.28	1.02	0.88
Derivatized - MS/MS PE NeoGram MS2 Kit	289	11.20	1.39	1.60	1.02	0.85
Non-derivatized - MS/MS PE NeoGram MS2 Kit	89	12.13	1.28	1.76	0.97	0.92
Derivatized-MS/MS Chromsystems Kit	10	8.80	0.45	0.45	0.64	0.67

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7x. 2008 Quality Control Data
Summaries of Statistical Analyses

STEAROYLCARNITINE (μmol C18/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 765 – Enriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	679	0.80	0.11	0.21	0.81	0.87
Non-derivatized MS/MS Non-kit	70	0.67	0.08	0.14	0.64	0.82
Derivatized - MS/MS PE NeoGram MS2 Kit	275	0.75	0.11	0.13	0.77	0.85
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	0.73	0.08	0.11	0.73	0.88
Lot 766 – Enriched 1 μmol/L whole blood						
Derivatized - MS/MS Non-kit	682	1.66	0.24	0.41	0.81	0.87
Non-derivatized MS/MS Non-kit	70	1.48	0.13	0.26	0.64	0.82
Derivatized - MS/MS PE NeoGram MS2 Kit	280	1.60	0.20	0.23	0.77	0.85
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	1.56	0.18	0.20	0.73	0.88
Lot 767 – Enriched 2 μmol/L whole blood						
Derivatized - MS/MS Non-kit	685	2.56	0.32	0.66	0.81	0.87
Non-derivatized MS/MS Non-kit	60	2.22	0.19	0.39	0.64	0.82
Derivatized - MS/MS PE NeoGram MS2 Kit	279	2.50	0.35	0.37	0.77	0.85
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	2.55	0.31	0.32	0.73	0.88
Lot 768 – Enriched 5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	686	5.14	0.63	1.44	0.81	0.87
Non-derivatized MS/MS Non-kit	60	4.78	0.43	0.89	0.64	0.82
Derivatized - MS/MS PE NeoGram MS2 Kit	273	4.99	0.55	0.67	0.77	0.85
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	5.13	0.67	0.71	0.73	0.88

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

STEAROYLCARNITINE (μmol C18/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 861 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	769	1.01	0.19	0.32	0.93	0.95
Non-derivatized MS/MS Non-kit	89	0.82	0.10	0.16	0.78	0.81
Derivatized - MS/MS PE NeoGram MS2 Kit	284	0.85	0.13	0.16	0.80	0.84
Non-derivatized - MS/MS PE NeoGram MS2 Kit	68	0.86	0.10	0.14	0.77	0.94
Derivatized-MS/MS Chromsystems Kit	10	0.58	0.06	0.06	0.49	0.62
Lot 862 – Enriched 1 μmol/L whole blood						
Derivatized - MS/MS Non-kit	770	1.76	0.28	0.49	0.93	0.95
Non-derivatized MS/MS Non-kit	90	1.45	0.19	0.31	0.78	0.81
Derivatized - MS/MS PE NeoGram MS2 Kit	283	1.52	0.23	0.31	0.80	0.84
Non-derivatized - MS/MS PE NeoGram MS2 Kit	68	1.60	0.18	0.20	0.77	0.94
Derivatized-MS/MS Chromsystems Kit	10	1.01	0.12	0.12	0.49	0.62
Lot 863 – Enriched 2 μmol/L whole blood						
Derivatized - MS/MS Non-kit	769	2.87	0.47	0.78	0.93	0.95
Non-derivatized MS/MS Non-kit	88	2.51	0.23	0.43	0.78	0.81
Derivatized - MS/MS PE NeoGram MS2 Kit	284	2.53	0.34	0.46	0.80	0.84
Non-derivatized - MS/MS PE NeoGram MS2 Kit	68	2.63	0.30	0.37	0.77	0.94
Derivatized-MS/MS Chromsystems Kit	10	1.73	0.16	0.16	0.49	0.62
Lot 864 – Enriched 5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	772	5.71	1.21	4.74	0.93	0.95
Non-derivatized MS/MS Non-kit	88	4.80	0.44	0.82	0.78	0.81
Derivatized - MS/MS PE NeoGram MS2 Kit	274	4.98	0.66	0.81	0.80	0.84
Non-derivatized - MS/MS PE NeoGram MS2 Kit	67	5.48	0.55	0.87	0.77	0.94
Derivatized-MS/MS Chromsystems Kit	10	3.63	0.25	0.25	0.49	0.62

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

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